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The Effects of an Accelerated Physical Therapy Protocol on Patients Receiving Standard Open Rotator Cuff Repairs: An Outcome Study

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THE EFFECTS OF AN ACCELERATED PHYSICAL THERAPY PROTOCOL ON PATIENTS RECEIVING STANDARD OPEN ROTATOR CUFF REPAIRS: AN OUTCOME STUDY

By

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This Independent Study, submitted by David J. Kohns in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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(Chairperson, Physical Therapy)

PERMISSION

Title	The Effects of an Accelerated Physical Therapy Protocol on Patients Receiving Standard Open Rotator Cuff Repairs: an Outcome Study
Department	Physical Therapy
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Date 12-17-99

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ABSTRACT

The purpose of this study was to determine the functional outcomes of patients who have undergone physical therapy treatment following rotator cuff surgical repair. Sixty-eight rotator cuff repairs performed between September 1995 and July 1999 at St. Alexius Medical Center in Bismarck, North Dakota were reviewed retrospectively. Of the 59 patients with rotator cuff repairs who met the criteria for this study, there were 34 males (57.6% of the cases) and 25 females (42.4% of the cases) included in the study. The mean age of the patients was 64.3 years, ranging from 38 to 80 years, with a median age of 67 years.

Of the 59 rotator cuff repairs analyzed, 38 of the patients met the criteria categorized as favorable or unfavorable. Thirty patients were categorized as having favorable outcome results. These patients had the following distributions: 16 male, 14 female; 5 small tears, 9 medium tears, 14 large tears; 65.5 mean age; 50% dominant shoulder involved; mean 6.8 outpatient physical therapy visits. In comparison, the 8 patients who were categorized having unfavorable outcome results had the following characteristics: 6 male, 2 female; 2 small tears, 3 medium tears, 2 large tears; 63.4 mean age; 66.7% dominant shoulder involved; mean 8.0 outpatient physical therapy visits.

From the above encouraging results it can be surmised that surgical repair and rehabilitation of rotator cuff tears at this healthcare facility has produced very favorable clinical outcomes. The demographics of the patients in this study indicate that the mean age was older than the age of the general population. Over one-half of the patients treated had large rotator cuff tears. Other demographic characteristics of patient outcome profiles are included in this study. Physical therapy rehabilitation was beneficial in enabling patients to achieve favorable outcomes.

CHAPTER I

INTRODUCTION

The Role of Outcomes Research in Managed Care

Donabedian states that the overall goal of managed care is to "allocate resources to produce the greatest improvement for its enrollees as a whole."[1(p 1171)] With budgeted resources managed care facilities attempt to utilize those resources that have proven to be clinically cost effective. The steady rise in managed care facilities in the United States has increased the tendency of managed care influencing medical practices. Pressure is being placed upon the physical therapy profession to show justification for services provided and reimbursements requested. With an increased demand for accountability, the area of healthcare outcome research has become a valuable resource in justifying all medical services.[1]

Justification of medical services can further improve various fields of medicine, including physical therapy, by providing a professional identity and rational. A professional identity can better define the rights and responsibilities of a profession and thus assist the field in confidently accepting the challenges of recent managed care changes.[2,3] Managed care demands that the medical community defines what treatments

work and for whom they work. Those fields that can be held accountable for their claims will survive and grow stronger.[4]

Managed health care facilities can be viewed as customers of medical service. Schoenbaum states that, "providing treatments that are supported by evidence of effectiveness and cost-effectiveness should be the desired goal of any health care delivery system. Evidence-based treatment requires clinical guidelines, criteria reviews, performance measures, and standards of quality."[4(p 273)] Outcomes research can be utilized to provide such evidence.

Outcome studies encompass a wide variety of medical research, such as surgical techniques, rehabilitation treatments, productivity, product utilization, patient satisfaction, etc. This study is an analysis of patient clinical outcomes following rotator cuff repair and rehabilitation. The data reported includes patient demographic variables and functional outcomes. This study was conducted with the collaboration of St. Alexius Medical Center in Bismarck, North Dakota. The results of this study will assist St. Alexius Medical Center in providing services that are not only the most time efficient and cost effective, but also the most medically appropriate.

Purpose of this Study

The purpose of this study was to describe clinical outcomes of patients who have undergone physical therapy treatment following rotator cuff repair using a standard open surgical procedure.

Objectives of the Study

The outcome data analyzed will include: range of motion, muscle strength, pain level, and functional use of surgically repaired shoulders. Additional information will be

provided regarding the effects of various demographic variables (gender, age, size of tear, etc…) on the outcome data. The data will be collected at predetermined intervals up to two years post operatively. Objectives of this study include:

1. A literature review of contemporary issues and techniques of outcomes research
2. A literature review of contemporary issues related to rotator cuff structures, functions, and surgical repairs.
3. The establishment of relative intervals in which range of motion of the surgically repaired shoulder is compared to the uninvolved shoulder.
4. The establishment of relative intervals in which muscle strength of the surgically repaired shoulder is compared with the uninvolved shoulder.
5. The establishment of relative intervals in which a patient achieves a pain free surgical shoulder using a 0-10 pain scale, where 0 indicates no pain and 10 indicates excruciating pain.
6. The establishment of relative intervals in which a patient achieves functional use of the surgically repaired shoulder as recorded by the Upper Extremity Functional Assessment Form.
7. The identification of patient demographic variables (gender, age, size of tear, etc.) and their relationship to the range of motion, functional uses of the shoulder, and pain levels at three weeks, six weeks, six months, one year and two years post-operatively.

Benefits of this Study

The benefits of outcomes research include the determination of the most effective and efficient ways to achieve desired goals. Improvements in the quality of medical service will ultimately result from such analysis. Data from this study of rotator cuff repair surgery and rehabilitation will benefit third party payers (insurance companies, Workers Compensation, Medicare/Medicaid, etc.) who provide reimbursement for health care services. These groups will receive improved services for their investment. St. Alexius Medical Center will be provided with quantitative data to better analyze rotator cuff surgical and rehabilitation outcomes. Individual health care providers will have feedback to evaluate their performance as they strive to achieve Continuous Quality Improvement (CQI). Most importantly, future patients will benefit from more functionally effective and cost efficient treatments. The data from this study will be made available to St. Alexius Medical Center, the University of North Dakota Physical Therapy Department and the Health Science Library as a future reference for rotator cuff rehabilitation and outcomes research. Outcomes research is a valuable tool whereby physical therapy can justify and self-govern their profession. The future of health care demands that each component must be accountable for the effectiveness and efficiency of their service.

CHAPTER II

OUTCOMES RESEARCH LITERATURE REVIEW

In the search for quality health care, outcomes research attempts to identify the components of quality. Keller[5] describes quality by the following equation:

"Quality = Efficacy + Effectiveness + Appropriateness"[5(p 488)]

In its most simplistic form, the definition of an outcome is the end-result of the treatment and effectiveness of care.[6]

Outcomes Research – A Process of Identifying Quality

The definition of the outcome may vary subjectively based on the perspective of the researcher. A health care provider, such as a physical therapist, may focus on the changes in health status based on a specific condition and related treatment. A patient may focus on the level of function following a treatment program. An employer may be concerned with number of days lost, productivity levels, and worker's compensation rates. Even at a societal level there are issues affecting whether the health care system is functioning as efficiently and effectively as possible.

The basic components of an outcomes measurements include: 1) a plan defining the outcomes of interest, 2) applicable data variables, 3) standardized data collection protocols, 4) technology for data input and analysis, and 5) constructive input by all involved in the process.[5,6] Hart[7] states that the instruments for collecting outcome data

must include aspects of "reliability, internal consistency, validity, sensitivity, specificity, responsiveness to change, and cumulative effects of multiple professions and time."[7(p 1)]

Recent changes in health care have shifted the focus of treatment outcomes away from traditional clinical quantitative analyses to patient functional improvements and quality of life issues. Treating the whole patient has now come to include survival rates; states of physiological, physical, and emotional health; and satisfaction with heath care service. Outcomes research has likewise shifted its focus to provide both clinical quantitative analysis as well as patient focused data.[6]

Hart[7] suggests that outcomes research requires, "cultural and personal philosophic changes, planning, time, money, dedication, continuous attention to detail, continuous nurturing, and constructive criticism, along with concomitant change."[7(p 1)] Outcomes research will utilize a wide variety of expertise, including: clinicians, administrators, statisticians, methodologist social scientists and health economists.[5]

General Research Issues Pertaining to Outcomes Research

In addition to defining outcomes, other general research issues that must be considered include: timing, attribution, level of analysis, and databases. The *timing* of data collection for a repeated measures study must be within reason to achieve desired outcomes. It is suggested that data collection be conducted at various points during the process. Patient *attribution* must be considered, as the health of an individual may be dependent on a variety of interactions. A researcher may have difficulty separating the multiple factors that contribute to an outcome. The current theories of poly-pharmacy, medical specialization, reimbursement, and ethical and political issues cloud the capability to isolate individual interventions. Researchers must use caution to account for

the variations that may occur due to attribution. Attribution can be accounted for through analysis of baseline comparisons, patient demographics, specific treatments, possible environmental factors, and additional clinical intervention. The *level of analysis* is dependent on the desired research outcomes. Certain outcomes may provide information on a specific treatment, provider, and/or health care system. A *database* for further study should be formulated with vast amounts of data collected during the research process. Developing such a database is difficult based upon time and resources commitments, confidentiality issues, and a general lack of standardized documentation in the healthcare field.[6] Once outcome data has been collected and analyzed it must be presented in an honest and easily interpreted manner. When presented to the health care provider, outcome data can be used as an educational tool when developing and improving practice guidelines.[8]

Importance of Outcome Studies – Utilization for Cost Analyses

Hart[7] states that, "merging patient's perception of their functional abilities and well-being with the therapist's perception of the clinical change bolstered by the patient-specific functional scale will provide a powerful description of treatment effectiveness."[7(p 2)] Outcomes research can assist in defining value and calculating specific outcomes data. Hart[7] suggests that, "Practices will be able to market value and be prepared to go at risk with confidence for captivated contracted manage care plans by patient diagnosis and severity, all risk-adjusted."[7(p 2)]

An outcomes study by Savoie et al[9] identifies the medical cost for treatment of rotator cuff repairs. This study identified the cost effectiveness of rotator cuff repair for worker's compensation patients. The study included 50 patients who had been

determined to have "successful" results following a rotator cuff repair. The cost included all evaluations, diagnostic studies, surgical repair, physical therapy and work hardening from the date of initial injury. The average cost was $50 302.25 per patient with an average of 11 months before returning to unrestricted duty. Patients referred to specialists immediately after the rotator cuff injury had an average cost of $25 870.64 with an average work returning time of seven months. Patients managed with a "gatekeeper" system averaged $100 280.10 with an average returning time of 18 months. Under the "gatekeeper" system a designated healthcare provider, such as a family physician, will determine whether further medical assistance will be sought or allowed. Savoie et al[9] conclude that immediate referral to a specialist for patients with a rotator cuff tear can result in decreased cost and earlier return to work. The results of this study may differ according to variations in specific chronic rotator cuff tears as with well as differences in demographic factors.

A study by Vitale et al[10] reported the geographic variations in the rates of operative procedures, including rotator cuff repairs. The results of this study indicate: 1) significant geographic variations exist in the rates of operative procedures, 2) population density showed a significantly negative relationship with the rates of operative procedures and 3) the availability of physicians did not significantly affect the rates of operative procedures. The authors stated that, "residents in states with low population density (for example North Dakota, Idaho, Wyoming, and Montana) may have higher prevalence of arthritis, overuse syndromes, and trauma as a result of the more strenuous, labor-intensive life style in these rural areas, which have large agriculture work force."[10(p770)] An injury, such as a rotator cuff tear, will be more disabling for these

physically demanding occupations. As a result, these individuals may be more willing to seek operative treatment.[10]

Outcome Research Controversies

When clinical decision making is taken away from the clinicians, control issues will exist. Many of the comments in opposition to outcome research relate to a general statement made by Mambourg[8] who states, "Often you're using data that was not designed to measure clinical quality, and you're using it to make decisions that affect clinical quality."[8(p 32)]

A review of various medical journals provides insights into the medical professions' opinion of outcomes research. These opinions illustrate that controversies exist in outcomes research. In response to an article entitled "Outcomes Research and Cost Containment" in the *New England Journal of Medicine*, Hadorn[11] stated that "Payers are lining up to use outcome information to tailor their benefits packages." Lest states in the February 1996 edition of *Michigan Medicine* article entitled "Physicians Speak Out on Outcomes Measurements" that healthcare professionals may, "fear that data will be used against them, and that the resultant guidelines will be so rigid and static as to lead to "cook book" medicine."[8(p 31)] In the same article, Billi[8] suggests,

> Outcomes are highly susceptible to misuse, to the great disadvantage to the patient and their physicians. When outcomes of individual physicians are released to the public and their employers, great harm can be done to both the patient and the physician. These groups always lack the information to accurately interpret and understand the outcomes, and they may act on incomplete or inaccurate information.[8(p 33)]

On a societal level, controversies related to outcomes research exist when monetary values are assigned to the value of life. Donabedian[1] states that,

> If, as is often the case, the average earnings signify the worth of a person, women are devalued relative to men, nonwhites relative to whites, and the aged might seem to be worth little or nothing at all. And who knows what other strata of worthiness might the seduction of this approach to monetary valuation create?[1(p 1170)]

This is a rather extreme view; however, it does pose an interesting insight into the power of cost-benefit decisions. Schoenbaum states that, " clinical controversies often arise when benefit-risk or benefit-cost differences of alternative approaches are qualitatively dissimilar."[4(p 273)]

From a research standpoint outcome research has been subjected to scrutiny based on reliability, validity, responsiveness and practicality. These are common issues in research, especially the selection of appropriate subjects, instruments, statistical analyses, and the reporting of results. The reliability of data collection in medicine, including physical therapy, has been hampered by a lack of uniformity in clinical measurements. Many of the measurements, such as perceived quality of life and pain, are subjective accounts that are assigned quantitative values. Patients may overestimate or underestimate their perception based on psychological, litigation, or other motivational factors. Outcome research should utilize data collection techniques that have been universally accepted by a majority of the medical field and recognize patient variability in their responses.[1,8]

Assessment of outcomes tends to focus only on the end result of treatment. This assumes that the outcome is a direct result of the treatment. Outcomes research does not account for improvements due to placebo effects, spontaneous recovery, or co-intervention provided by other practitioners.[12] Outcomes research should include a detailed description of the treatments involved in reaching the finale results. This research will help in directing the focus to the steps required for achieving favorable outcomes.

An additional controversy related to outcomes research is reporting the data. As previously stated, healthcare professionals may feel threatened by outcomes information if the data is viewed outside of the context of the actual situation.[8,11,13] The goal in reporting results of any research must be kept in mind by all involved. As stated earlier the goal of outcomes research can be viewed as an analysis of the end-results of treatment and effectiveness of care.[6] Rothstein states that, "Research designed to be self-serving is not research; it is propaganda. Research assuming to prove foregone conclusions is not research; it is merely old biases in new packages."[14(p 1)]

Commentary on Outcomes Research Literature Review

The overall objective of this Outcomes Research Literature Review Chapter was to familiarize the reader with contemporary challenges of managed care; justification of medical services; and outcomes research, procedures, issues, and controversies. The importance of outcome research was stressed throughout this chapter. Outcome studies by Savoie et al[9]; and Vitale et al[10] offer insights regarding the importance of outcome research. The findings of outcomes studies can directly influence medical guidelines for care providers and third party payers.

Outcomes research does have room for improvement. Keller[5] offers the following suggestions specifically for the direction of further shoulder repair outcomes research.

1. Define and standardize terminology for the diagnosis, treatment and assessment of different shoulder pathologies.
2. Develop and validate a practical, and patient-oriented assessment tool containing a minimal data set of information about function and satisfaction. This set of information should be common to all patient evaluations.
3. Develop strategies for assessing outcome in the community setting using this tool.
4. Define the extensions to the minimal data set for assessing the outcomes in specific populations.
5. Standardize tools for the evaluation of strength, range of motion and stability in clinical and experimental setting.
6. Correlate the patient-orientated tool with the results of objective assessments.
7. Establish strategies for encouraging participation in outcome research within the community of physicians involved in treating shoulder problems.
8. Use the results of outcome research to work toward optimal and uniform quality of care for shoulder problems through standardization, effective and appropriate practice guidelines.

9. Use the results of outcome research to demonstrate the value of shoulder management protocols.[5(p 486)]

These principles attempt to provide much needed uniformity to rotator cuff repair outcome research. Keller[5] stresses issues of validity and reliability in developing a significant database for use in treatment guidelines. Keller's[5] principles were helpful in the development of this study involving rotator cuff repair outcomes.

CHAPTER III

ROTATOR CUFF LITERATURE REVIEW

The human upper extremity has allowed great advancements for our species. The ability to maneuver our hands to perform various tasks is an invaluable skill. The shoulder girdle provides the proximal stability to allow for distal mobility of the hand. When exploring the marvels of the human upper extremity it is important to understand the structures and functions of the shoulder girdle. The shoulder girdle, also referred to as the pectoral girdle, is made up of the clavicle, scapulae and various support structures. It provides attachment for the humerus to the rest of the body. The shoulder girdle provides a fairly stable, yet mobile structure from which the rest of the upper extremity is allowed to perform more intricate activities.[15] In addition to the structures and functions of the shoulder girdle, the topics of dysfunction, evaluation, and treatment must also be considered. A thorough exploration of the intricacies of the shoulder can provide insights regarding how humans have been able to use these anatomical advantages to succeed as well as the limitations incurred with related injuries.

Anatomy of the Shoulder Girdle and Rotator Cuff

The shoulder girdle is comprised of the scapula and the clavicle. It provides attachment for the humerus to the axial skeleton.[15] These structures are linked through a series of 5 components, or joints, which add to the structural support and allow for biomechanical function of the shoulder girdle. These joints include the scapulothoracic (ST), the sternoclavicular (SC), the acromioclavicular (AC), the glenohumeral (GH) and the coracoacromial arch (CA), also referred to as the suprahumeral joint. The CA joint plays a substantial role in rotator cuff pathologies. The CA is considered by some to be a "false joint"; however, it does play a substantial role in shoulder function and dysfunction, therefore it is considered with the other joints of the shoulder girdle.[16] Figure 1 illustrates the various joints and osseous structures involved in the shoulder girdle.

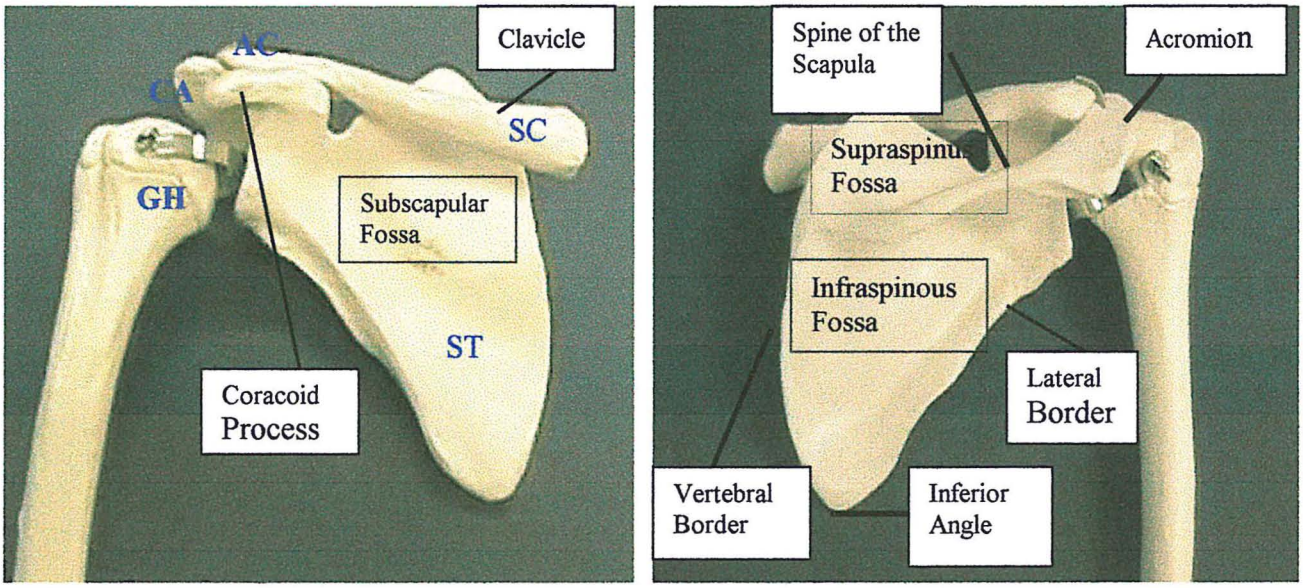

Figure 1. Joints and Osseous Structures of the Shoulder Girdle: Scapulothoracic (ST), Sternoclavicular (SC), Acromioclavicular (AC), Glenohumeral (GH) and Coracoacromial arch (CA)

The CA is comprised of the coracoid process anteriorly, the coracoacromial ligament superiorly and the acromion posteriorly. The function of the CA is to protect the following structures from superficial to deep: subacromial bursa, supraspinatus tendon, joint capsule, long head of the biceps tendon and humeral head. Each of these structures may become clinically involved due to traumatic or overuse injuries. The CA can reduce traumatic injuries to these structures, such as superior dislocation of the humeral head; however, the close approximation of these structures under the CA can make them susceptible to impingement conditions.[16,17] The CA forms the roof in what is referred to as the supraspinatus outlet. Figure 2 illustrates the CA and the surrounding structures.

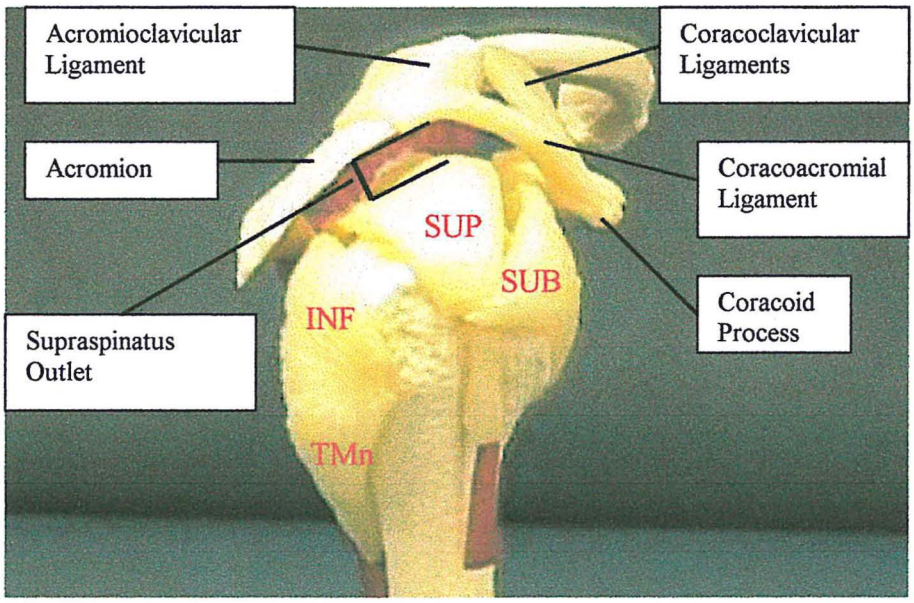

Figure 2. Lateral View of the Shoulder Girdle Highlighting the Supraspinatus Outlet; Supraspinatus (SUP), Infraspinatus (INF), Teres Minor (TMn), and Subscapularis (SUB).

The supraspinatus outlet allows for an average of distance of 7 to 14 mm between the ligament and the humeral head.[18] A radiographic study by Weiner and Macnab[17] found that the distance was less than 6 mm in 50% of diagnosed rotator cuff tears. Diagnostic imaging indicating less than 11 mm space may indicate an impingement and rotator cuff pathology.[18,19] Magnetic resonance imaging (MRI) has been shown to be a valuable tool in measuring the supraspinatus outlet and differentiating various soft tissue conditions including bursitis, tendinitis, and rotator cuff injuries.[18,20]

Additional Shoulder Structures

The glenoid labrum, GH joint capsule, the GH ligaments, and the surrounding muscles provide further support for the GH joint. The GH joint is aided structurally by the glenoid labrum, which functions to increase the total available articular surface. The glenoid labrum is a fibrocartilaginous rim that originates on the periphery of the glenoid fossa. This labrum is a continuation of the GH joint capsule and it blends superiorly with the tendon of the long head of the biceps brachii muscle.[15]

The fibrous GH joint capsule is approximately twice the size of the humeral head.[20] At rest the GH joint capsule will allow up to 1 inch of distraction for increased mobility. Obviously, a majority of the support for the GH joint is provided by the GH ligaments and to a greater extent the rotator cuff muscles. The GH ligaments as horizontal pleats in the anterior capsule. The 3 GH ligaments (superior, middle, and inferior), along with the coracohumeral ligament, provide resistance to anterior glide of the humeral head, especially during external rotation. The coracohumeral ligament runs superiorly from the coracoid process and blends with the superior GH joint capsule and the supraspinatus tendon as it inserts on the greater tubercle.[15] The coracohumeral

ligament also provides valuable passive support of the GH joint against the force of gravity.[15,17] The inferior portion of the GH joint has been found to be the least supported area. Interestingly, more dislocations and instabilities are noted to be in an anterior direction due increased incidences of anterior forces compared to inferior forces.[16]

Additional structures involved with the shoulder complex include the subacromial bursa, the subscapular bursa, and blood and nerve supply. The subacromial bursa is a large bursa located between the deltoid muscle, the supraspinatus tendon, and the GH joint capsule. The subacromial bursa facilitates movement of the supraspinatus tendons and the deltoid. The subacromial bursa may become clinically involved with CA impingement conditions. The subscapular bursa is located between the tendons of the subscapularis and the inferior portion of the coracoid process. The subscapular bursa facilitates movement of the subscapularis tendons. Blood supply to the shoulder joint is from articular branches of the anterior and posterior circumflex humeral arteries. Nerve supply to the shoulder joint includes articular branches from the suprascapular, axillary, and lateral pectoral nerves.[15]

Osteokinematics of the Shoulder

The biomechanics of the shoulder girdle can be thought of as 5 joints working together to provide the greatest mechanical advantage possible. Again the issues of stability and mobility greatly influence the biomechanics of the shoulder girdle. The related muscle groups can be viewed as "dynamic stabilizers" of the shoulder girdle. The concept of dynamic stabilization is in essence a combination of both the mobility and stability required by the shoulder. Motions of the shoulder girdle can be explained in terms of motions of the humerus, scapula, and clavicle.[21, 22]

Humeral Motions

Isolated motions of the humerus are difficult to separate from the other related joint motions. The following principles can be applied to humeral motions.

- The GH joint allows up to 120 degrees of passive abduction motion until the humeral neck impinges against the acromion process. With the scapula fixated the humerus can only be actively abducted to 90 degrees due to the decrease in abduction force of the deltoid and supraspinatus. Full scapula motion is required to maintain the mechanical advantage of the involved muscles and allow for the full 180 degrees of abduction.[21]
- The humerus externally rotates approximately 90 degrees during abduction to allow the greater tuberosity of the humerus to pass below the coracoacromial arch. This action emphasizes the importance that the external rotators (infraspinatus and teres minor) have during full active abduction. When internally rotated to end range, the humerus can only be passively abducted to 60 degrees due to impingement of the greater tuberosity against the coracoacromial arch.[21]

Scapular Motions

Scapular motions are more accurately referred to as "scapulohumeral rhythm". The scapula must respond in a timely manner to maintain the mechanical advantage of the involved structures. A dysfunction of the scapulohumeral rhythm can result in decreased motion and or impingement conditions. The following principles can be applied to scapulohumeral rhythm.

- Humeral elevation is always accompanied by scapular rotation. The concept of the golf ball and tee can describe the role of the scapula in supporting the

humerus. As the ball (humeral head) rotates, the tee (glenoid of the scapula) positions itself in attempt to stay under the ball and provide support.[22]

- Various theories debate timing of the scapula motion; however, many agree that there is a resultant 2 to 1 ratio of GH to ST motion during shoulder elevation (approximately: GH = 120 degrees, ST = 60 degrees; 2:1 ratio).[22]

Clavicular Motions

The structural attachment of the clavicle to the relatively stable sternal portion and the mobile scapular portion implies a direct relationship between clavicular-scapular motions. The following principles can be applied to clavicular motions.

- Singleton[22] describes the scapula as possessing approximately 60 degrees of upward rotation. The clavicle accommodates this 60 degrees rotation with 30 degrees of motion at both the AC and the SC joints. Thirty degrees of motion at the AC joint are completed in the first 90 degrees of shoulder abduction. Thirty degrees of motion at the SC joint occurs in two 15 degree intervals. These intervals occur at the early phase, less than 30 degrees, and late phase, greater than 135 degrees, of humeral abduction.[22]

Rotator Cuff – Structure and Biomechanics

The rotator cuff muscle group is also referred to as the SITS muscles (Supraspinatus, Infraspinatus, Teres minor, and Subscapularis). The main function of the rotator cuff is to provide dynamic stabilization to the shoulder. Figure 3 illustrates the orientation of the rotator cuff muscles.

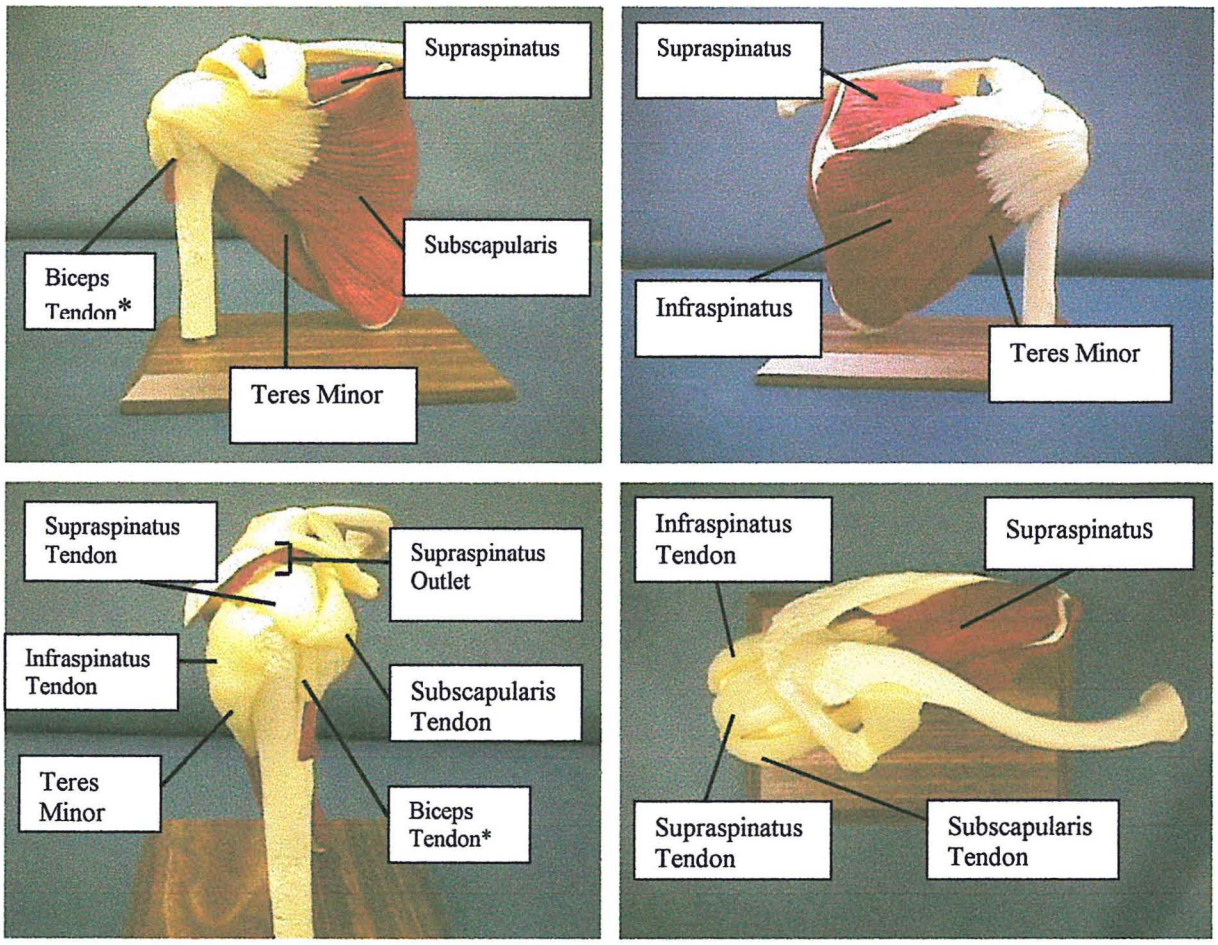

Figure 3. Rotator Cuff Muscles and Orientation: Supraspinatus, Infraspinatus, Teres minor, and Subscapularis.
*Note: the long head of the biceps tendon is often involved in rotator cuff injuries.

Clark and Harryman[17] have determined that, "the tendons of the rotator cuff fuse into a continuous band at or near their insertion onto the tuberosities of the humerus."[17(p17)] Through microscopic study Clark and Harryman[17] have described 5 layers that make up the rotator cuff insertion. The layers are organized as follows:

- Superficial fibers of the coracohumeral ligament
- Closely packed tendon fibers directed from muscle belly to humerus.
- Less uniform tendon fibers.

- Loose connective tissue layer with collagen fibers running perpendicular to the tendon fibers.
- This layer also contains the deep fibers of the coacohumeral ligament.
- Deep continuous capsular layer between the humerus and the glenoid.

Clark and Harryman[17] suggest that the variation in fiber orientation may contribute to the occurrence of intrasubstance tears. The individual muscles of the rotator cuff function in harmony with other related muscles to produce various motions at the shoulder. The rotator cuff is clinically susceptible to both traumatic and chronic overuse injuries.[16,23-26] The following section reviews normal biomechanics of the rotator cuff and explores factors involved in rotator cuff pathologies.

Biomechanics of the Supraspinatus

The supraspinatus fossa of the scapula is the origin of this clincally involved muscle. The tendon runs laterally underneath the CA and inserts on the superior facet on the greater tubercle of the humerus. The supraspinatus is innervated by the suprascapular nerve (C4, C5, C6). The main action of the supraspinatus is to assist the deltoid in abducting and flexing the humerus.[15] The supraspinatus is one of the rotator cuff muscles that provides dynamic stabilization of the glenohumeral joint. The line of pull for the supraspinatus provides positive translatory force resulting in compression of the humeral head into the glenoid fossa.

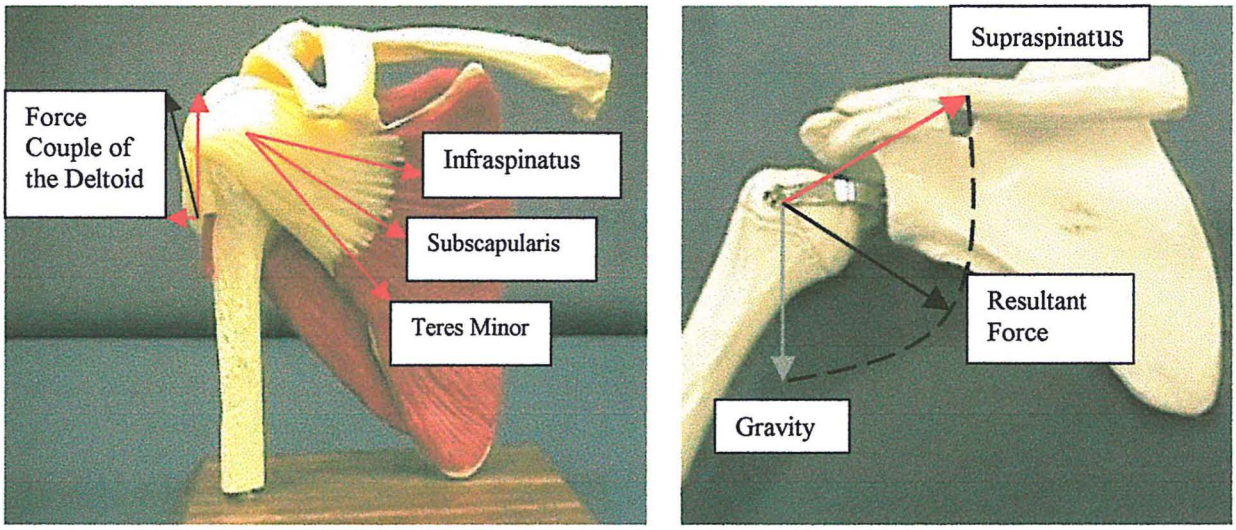

Figure 4. Resultant Forces from the Rotator Cuff and Deltoid Muscles.

When analyzing Figure 4 the value of the compressive force of the supraspinatus is apparent. A downward force from gravity and the other rotator cuff muscles in combination with the superior/medial force of the supraspinatus results in a downward sliding motion along the articular surface.[16] This motion is in accord with the arthrokinematics that occur at the GH joint as the convex humeral head rolls and glides on the concave glenoid fossa during abduction.[27]

In a study by the Mayo Clinic, Ito et al[17] proposed that the anterior portion of the supraspinatus tendon had the highest tensile strength. Another study by Nakajima et al[17] evaluated the structure of the supraspinatus tendon. They suggest that the joint side of the tendon is more susceptible to mechanical failure compared to the bursal side. This is in accord with the higher rate of reported articular-side tears.[17]

Biomechanics of the Infraspinatus, Teres Minor and Subscapularis

The location of insertion of the infraspinatus, teres minor, and subscapularis also provides structural support to the GH joint. With the insertion on the lesser tubercle of

the humerus, the subscapularis provides anterior support to the GH joint. The infraspinatus and teres minor likewise offer posterior support to the joint with their respective insertions on the middle and inferior facets on the greater tubercle.[16]

Compared to the supraspinatus, the remainder of the rotator cuff muscles provide both similar and unique functions. Returning to Figure 4, the line of pull for the infraspinatus, teres minor, and subscapularis provides a negative translatory force to counter the positive forces of the deltoid and supraspinatus. This negative force is an important compressive component for the stability of the GH joint. The infraspinatus, teres minor, and subscapularis are critical in providing a downward/medial force on the humeral head. An imbalance in this force may result in a superior translation of the humeral head and may lead to CA inpingement.[16]

Another function of the infraspinatus and teres minor is to cause external rotation of the humerus during abduction. By externally rotating the humerus, the greater tuberosity of the humerus is allowed to pass underneath the CA.[21] The infraspinatus and teres minor may become clinically involved in overhead athletes. These muscles are recruited to contract eccentrically to decelerate the humerus during the follow-through phase of throwing. Repetitive, high force throwing can lead to inflammation, swelling and eventually impingement.[26]

Rotator Cuff Injuries - Cause, Evaluation and Treatment

A vast amount of literature has implicated the supraspinatus in most rotator cuff pathologies.[16,23-26,28,29] It is clinically relevant to mention that the supraspinatus has an area of decreased vascularity just proximal to the greater tuberosity, approximately 1 cm medial to the insertion of the tendon. This area is often referred to as the "critical zone."

In a neutral resting position, the weight of the dependent arm causes compression of the tendon against the humeral head. This rather constant pressure tends to wring out blood from the relatively avascular tendon.[29] The critical area also produces impingement symptoms when compressed between the CA and the humeral head during abduction or flexion. According to Neer, mechanical compression of tendons under the CA is responsible for 95% of rotator cuff injuries.[17] The combination of decreased vascularity in the supraspinatus tendon and repetitive overhead activities has resulted in the supraspinatus becoming susceptible to degeneration.[23-26,28-30] Warren states, [26] "Generally these (rotator cuff tears) occur in the late 50s as a result of minimal trauma disrupting a weakened tendon that has already undergone degeneration over a period of years."[26(p 73)] The athlete who participates in sports such as baseball and tennis, may experience accelerated degeneration due to the repetitive nature of their sport.[26]

The cause of rotator cuff pathology can be viewed as multifactorial, including both extrinsic and intrinsic contributing factors. Extrinsic factors may include, but are not limited to, morphology of the CA, stress overload, repetitive use, and kinematic abnormalities. Similarly, intrinsic factors may include, but are not limited to, vascular supply to the tendon and orientation of tissue fibers. It is difficult to isolate one contributing factor as the "cause" of a rotator cuff injury. The combination of these factors should be analyzed as contributing factors.[17]

Neer[31] described impingement syndrome as progressing through 3 stages: Stage 1: hemorrhage and edema in the tendon; Stage 2: fibrosis and tendinitis; and Stage 3: rotator cuff tear, which may or may not be accompanied by a rupture of the biceps tendon and/or osseous changes. It has been reported that Stages 1 and 2 can be effectively

managed through conservative treatment including rest, anti-inflammatory medications, and physical therapy.[31]

Various opinions exist concerning when invasive treatment should be considered. Neer[31] recommends invasive treatment should a patient's condition persist for 18 months in spite of conservative treatment. Hawkins and Abrams[32] suggest "an operation after 1 year of symptoms if adequate conservative treatment was ineffective."[32(p 170)]

Physical Examination – Important Considerations for Valid Examination and Treatment

As with all physical examinations, a thorough *patient history* should be recorded. A patient with a rotator cuff injury may have a chief complaint of pain with eccentric resistance and/or overhead arm motions. The patient may also describe nocturnal discomfort and the inability lay on the involved side. Some patients will be able to report a specific traumatic event, whereas most will describe a chronic condition. *Observation* may indicate muscle atrophy about the supraspinatus and/or infraspinatus. The patient may also exhibit protective shoulder hiking. *Active range of motion* may be noticeably less than *passive range of motion*. A painful arc maybe evident with active abduction between 45-60 degrees and 120 degrees.[18] *Weakness* and *fatigue* are common with abduction, flexion, and external rotation. Post and et al[29] state, "patients with severe external rotator muscle weakness, loss of good active elevation (flexion), and increased crepitus generally appeared to have the larger tears."[29(p 89)] *Special tests* to assess the individual components of the rotator cuff include the external lag sign (infraspinatus and teres minor), the drop sign or empty can test (supraspinatus) and internal lag sign (subscapularis). These tests should be used to indicate possible rotator cuff involvement, but may not necessarily provide confirmation. Both the Neer's and Hawkins-Kennedy

Impingement Test should be conducted. Positive Yergason's and Speed's Test may indicate biceps involvement. The shoulder should also be assessed for joint stability with the load and shift test, the apprehension test, or the relocation test.[18] Paulos and Kody[33] stated, "It is especially important in differentiating those patients with primary impingement from those with impingement secondary to instability."[33(p 20)] *Sensory function* and *reflexes* should not be affected with a rotator cuff injury. *Palpation* may indicate tenderness over the rotator cuff.[18]

Surgical Repair of Rotator Cuff

Neer reported the key objectives in surgical repair of the rotator tendon included: 1) closure of the cuff defect; 2) elimination of the impingement lesions of the coracoacromial arch; 3) preservation the origin of the deltoid muscle; and 4) rehabilitation that prevents postoperative stiffness without disrupting the repair.[31] The emergence of the arthroscopic examination and repair has aided in the identification of involved structures, the ease of acromioplasty and the preservation of the deltoid origin.[25, 32] Arthroscopic repair of the rotator cuff has shown favorable results in the treatment of small and medium tears (3 cm or less).[34] Massive tears (larger than 3 cm) have been shown to have better success with an open repair.[30,35]

The study conducted through St. Alexius Medical Center was comprised exclusively of standard open repair with subacromial decompression surgery. The following is an extensive overview of the standard open repair. Brief summaries of the mini-open repair and the arthroscopic repair are also included.

Standard Open Repair of the Rotator Cuff

Cordasco and Bigliani[30] describe the open repair in 4 phases: 1) the approach, 2) the decompression, 3) the rotator cuff repair, and 4) rehabilitation. The following is an outlined description of a surgical procedure for an open repair of the rotator cuff as described by Cordasco and Bigliani[30] and Kunkle and Hawkins.[30]

The Approach

Patient is positioned in the beach chair position (approximately 60 degrees) with the head rotated to the contralateral side. Sterile drapes are placed around the involved shoulder. Intravenous antibiotics are administered and the procedure is conducted under general anesthesia, interscalene block, or general anesthesia with an interscalene block. Postoperative pain can be reduced with 0.5% bupivicaine.[30]

The bony landmarks are outlined with a marker. The 4 cm skin incision bisects the anterior acromion approximately midway between the acromioclavicular joint and the lateral border of the acromion. Following dissection through the subcutaneous layer, the deltoid muscle can be visualized. The deltoid muscle is detached from the anterior of the acromion, from the AC joint to the lateral acromion (approximately 2.5 cm). Kunkle and Hawkins state that a longitudinal split may be preferred to "reduce chance of retraction, improve reattachment, and perhaps better postoperative function."[30(p 143)] Cordasco and Bigliani[36] state that the split is begun, "approximately 5 mm anterior to the AC joint and extending directly laterally past the anterolateral corner of the acromion. The deltoid split is then extended for a distance of 3 to 5 cm laterally and slightly posterior to the anterolateral corner of the acromion in line with the fibers of the middle deltoid."[36(p 182)]

Additional glenohumeral joint abnormalities that may occur include "biceps tendon tears, labrum tears, SLAP lesions (superior labrum, anterior posterior), synovitis, and capsular contractures." These abnormalities occur in approximately 80% of patients with rotator cuff tears: however, only 20% will alter diagnosis or treatment. These abnormalities should be treated as indicated.[34]

The Decompression

Impingement may occur at the anterolateral CA, the anteroinferior acromion, and the AC joint. Decompression should be performed at these locations as indicated. For example, the anterior acromioplasty is performed with a 1inch osteome or an oscillating burr. The procedure is conducted from the anterior acromion and extending to the undersurface of the acromion (approximately 1.5 cm). The fragments are removed and the thoracoacromial artery is cauterized as needed.[30] It has been suggested by that the CA be removed in chronic conditions; however, the CA may be left in place in other cases to prevent superior translation of the humerus.[36]

The Rotator Cuff Repair - Options

Resection of the scar tissue is begun by identifying and resecting the superficial subacromial bursa. Following resection of the bursa the supraspinatus tendon should be apparent. The infraspinatus and teres minor can be visualized through extension and internal rotation of the arm. The subscapularis can be visualized with flexion and external rotation. Kunkel and Hawkins[30] classify a tear as small (less than 1 cm), moderate (1 to 3 cm), large (3 to 5 cm), or massive (larger than 5cm).[30] Following identification and classification of the tear, the distal 1 to 2 mm of the degenerative tendon is debrided.[34] The involved tendon is then mobilized in preparation for repair.

According to Cordasco and Bigliani[36], "to ensure a successful repair, the edges of the torn tendon should reach the anatomical neck of the humerus with the arm in a functional position of 10 to 15 degrees of forward elevation and 10 degrees of abduction."[36 (p 187)] If the infraspinatus is involved, caution should be used to prevent damage to the axillary nerve with a dissection below the level of the teres minor. At this time the coracohumeral ligament should be released with chronic tears.[36]

Two options are available for attaching the tendon to the trough, the transosseous repair and anchor attachment.[34-36] The transosseous technique utilizes a power burr to form a trough at the junction of the anatomical neck and the greater tuberosity of the humerus (20 mm x 5 mm x 5 mm).[35] McLaughin[35] suggests that, "A tendon cannot be expected to heal to naked cortical bone or cartilage. The trough provides a vascular bed for the tendon repair."[35(p 18)] In contrast Cordasco and Bigliani[36] state, "A deep trough is not necessary to facilitate healing and compromises bone."[36(p 187)] Drill holes are made toward the trough from 2 cm distal to the greater tuberosity.[30] Nonabsorbable braided polyester sutures have been shown to be effective; however, the suture type remains dependent upon surgeon's preference.[35] Kunkel and Hawkins[30] state, "the suture is directed from the tendon into the trough through the drill hole in the greater tuberosity, back through a different hole, through the trough, and again into the free edge of the tendon."[30(p 147)] Three to four sutures have been found to be adequate to achieve a water tight seal.

Ticker and Warner[35] state, "The anchor attachments have been developed as an alternative to transosseous sutures for rotator cuff tendon repair."[35(p 17)] The goal of the anchor is that it will allow firm fixation to the greater tuberosity.[34] The anchors should be

inserted into the subchondral bone adjacent to the articular surface to allow for a 90 degree line of pull with the humerus in 30 degrees of abduction.[40] Small tears generally require 2 anchors, whereas larger tears require 3 to 4.[34,35] The use of suture anchors may be acceptable in patients who do not present with chronic longstanding tendon tears and associated osteopenia (decrease in bone density) of the greater tuberosity.[35] Ticker and Warner[35] state, "The effectiveness of a suture anchor depends not only on the initial failure strength, but also on anchor size, anchor composition, suture type, size of drill hole, and available bone stock."[35(p 21)]

The repair is now assessed for tension. The point at which excessive tension occurs is recorded for postoperative positioning and rehabilitation. Ideally the arm is positioned at the side; however, if the repair is under excess tension an abduction brace can be used.[30] Depending of the procedure the deltoid is reattached to the anterior acromion or the split is repaired. The subcutaneous layer and the skin are reapproximated using absorbable sutures. The appropriate sling or abduction brace is positioned.[30,36]

Rehabilitation

The post-operative rehabilitation protocol used in this study is included in Appendix D. The effectiveness of rehabilitation of a rotator cuff repair can be aided by preoperative training by a physical therapist. The patient is instructed on the phases of rehabilitation, functional adaptations to wearing bracing, and a pulmonary home exercise program.[37] Postoperative rehabilitation is begun the first day with passive-assisted range of motion exercises. These exercises can be continued over the first 30 to 45 days, 4 times daily. In this time the patient may be seen by a physical therapist 2 to 3 times per

week. Cordasco and Bigliani[30] suggest that during the first 6 weeks exercises should include 1) pendulum exercises, 2) passive-assisted forward elevation to 140 degrees, and 3) supine passive-assisted external rotation using a stick to 30 degrees. After 6 weeks pulley exercises and extension of the humerus can be introduced. Between weeks 6 and 8, active-assisted and isometric exercises should be started including: supine external rotation/forward flexion and erect forward flexion with a stick. At 12 weeks a 1 to 3 pound weight can be added to the stick. Progressive dynamic strengthening is continued from 6 months through 12 to 18 months. Throwing athletes can begin specific throwing programs at a minimum of 12 months.[30,36]

The previous section is a general overview of a selected rehabilitation program. Individual programs may vary based on severity of injury, surgeon's preference, and patient's goals for treatment to name a few.[30] Timmerman, Andrews, and Wilks[38] site various factors that will determine the course of the rehabilitation protocol. These factors include patient's age, onset of injury, size of tear, work requirements, desired activity level and patient's motivational level. Research studies such as this outcome study can identify the degree of influence these factors can have on a patient's outcome.

Mini-open repair

The Mini-open repair of the rotator cuff begins with an arthroscopic examination. The rotator cuff tear and the GH joint are assessed for evidence of other pathology. Based on the extent of the tear, the decision will be made whether or not to continue with an open repair. If the tear is large or massive, a standard open repair is indicated. Regardless, the subacromial decompression is completed at this time arthroscopically. Timmerman, Andrews, and Wilks[38] state the decompression is performed

arthroscopically because, "less soft tissue dissection is necessary and the extent of the decompression can easily be directly visualized."[38(p 154)]

After the arthroscopic equipment is removed, the mini-open repair is begun with a longitudinal incision 4 to 5 cm long from the base of the acromion through the fibers to expose the torn rotator cuff. It is important not to split the deltoid farther than 5 cm distal to the acromion to avoid damaging the axillary nerve. At this point any further bursa should be resected to allow visualization of the rotator cuff. The involved tendon is mobilized. A high-speed burr is use to make 3 to 4 mm deep trough lateral to the articular surface. A minimum of 3 holes are drilled into the trough and suture anchors are inserted. Next, the sutures are attached to the tendon, approximately 1.5 cm proximal to the edge of the tendon. Any further defects to the rotator cuff are repaired, such as longitudinal tears.[37]

Paulos and Kody state[33] the distinct advantages to the Mini-open repair are, "1) there is no need to reposition, prepare, or drape the patient after arthroscopy, thus saving operating time, and 2) there is no need to detach the deltoid muscle, thus allowing more aggressive rehabilitation and reducing the possibility of deltoid nonunion."[33(p 25)]

Arthroscopic Repair of Rotator Cuff

The arthroscopic repair of the rotator cuff is begun with an approach utilizing 3 portals. The posterior portal is located 1.5 cm medial and 1.5 cm inferior to the posterolateral acromial border. The lateral portal is located posterior to the anterior acromial border approximately 5 cm lateral to the acromion. Finally, the anterior portal is located midway between the acromioclavicular joint and the anterolateral acromion. Each portal has a primary function, for example the arthroscope enters the posterior

portal, the cannula (the tube that allows fluid to exit the area) enters the lateral portal and the sutures are retrieved through the anterior portal. The remainder of the procedure includes: glenohumeral inspection, bursectomy, determination of the cuff reparability, identification of tear geometry, resection of the coracoacromial ligament, acromioplasty, greater tuberosity repair site preparation, anchor placement, suture placement and knot tying.[33]

The use of arthroscopic technology has provided surgeons with an effective diagnostic tool, as well as a means for performing procedures that previously required more invasive measures. Arthroscopy of the shoulder has progressed from basic diagnosis purposes, to decompression and now complete rotator cuff repair. The distinct advantage of arthroscopic repair is that the deltoid is not detached. This repair has aided in expediting the rehabilitation process. Suture management tends to be the most difficult aspect of the arthroscopic repair. These techniques require substantial practice to become proficient.[33]

The results of arthroscopic repair of the rotator cuff remain in the early stages of research. Recently, Tippet[39] reported that 16 months after arthroscopic repair 21 of 29 had satisfactory results based on the University of California at Los Angeles (UCLA) End Results Score (Appendix E). Wolf[39] reported that of 66 patients who underwent arthroscopic repair, 85% had good to excellent results and that 92% of the patients rated their outcome as satisfactory using the UCLA End Results Score.[39]

Outcome Factors Contributing to Rotator Cuff Repair

One of the main purposes of this study was to determine which variables have the most influence on long-term outcome measures including shoulder range of motion,

strength, pain level and functional ability. When analyzing factors that contribute to a patient with outcome measures, it is difficult to isolate one single variable as the determinant of an outcome. Factors such as patient's gender, age, dominant arm involvement, onset of injury, tear size, surgical procedure, surgeon, physical therapist and rehabilitation protocol all contribute to the eventual outcome. Determining the most influential variables can assist care providers as well as third party payers, with comparing results of similar patient profiles. Developing patient profiles can assist care providers in developing effective and efficient treatment protocols. For example, a patient with a massive rotator cuff tear may require a longer period of rehabilitation as compared to smaller tear. The results of outcomes studies can assist care providers in justification of their services.[19, 23, 36]

Patient Demographic Factors

As mentioned earlier the patient's age, gender and dominant arm involvement may contribute to the outcomes. The patient's age has been indicated in a number of studies as contributing to the outcome.[26,36-38, 40-43] Rotator cuff injuries generally occur in the patients in their late 50s as a result of minimal trauma to a weak tendon that has undergone years of degeneration. Injuries occurring under age 30 are rare and usually result from overuse or acute trauma.[26] Hattrup[43] compared patient results in relation to patient age and tear size. This study reported that "excellent" results decreased from 89.2% in small or medium tears to 80.4% in large or massive tears. The number of larger and massive tears was more frequent in patients over 65 years. This resulted in 77.4% excellent results in patients 65 years and over, compared to 88.6 % in patients younger than 65 years.[43]

Additional cofactors that may influence outcomes following a rotator cuff repair are gender and involvement of the dominant hand. Rotator cuff injuries are more common in men compared to females, but literature offers little support that gender has a significant influence on the outcomes following rotator cuff repair.[44] Rotator cuff injuries commonly occur on the dominant shoulder due to an increase in general use.[19,23,44] For example, baseball and tennis players usually have their throwing shoulders involved. For the general population, chronic tears can also be attributed to overuse of the dominant shoulder over a life time.[26] Similar to gender, a review of the literature offers little support concerning whether shoulder dominance has a significant influence on the outcomes of rotator cuff repair.

The 1997 *Guide to Physical Therapy Practice*[45] provides additional demographic factors that may modify the treatment plan. These factors include:

- The ability to transfer instructions to motor learning.
- Accessibility/Availability of resources.
- Caregiver consistency.
- Comorbidities.
- Level of patient adherence to intervention program.
- Preexisting systemic conditions or diseases.
- Support provided by family unit.

Discrepancies in Classification of Rotator Cuff Tear Sizes

The tear size, surgical procedure and surgeon are surgical factors that may effect the outcome of a rotator cuff repair. Throughout the literature the size of the tear has been

indicated as a significant contributor to the success of the outcome. [17,20,23, 26,29,30,33,34-36, 38,40,46,47] Hawkins reported that the size of the tear is directly proportional to the amount of shoulder active abduction.[48]

Discrepancies exist in the classification of rotator cuff tears. Various classification systems attempt to provide an anatomic-pathological description of the tear size. These systems may focus on the number of tendons involved, the amount of retraction of the tendons, the surface of the tear, or the largest linear dimension of the tear. Classification systems are crucial to outcome studies when comparing outcomes and variables that influence outcomes.

Classification discrepancies in rotator cuff tear size may also affect results of outcomes research. For example, an unfavorable result following a rotator cuff repair is often due to the difficulty involved in repairing and rehabilitating large or massive tears. A surgeon that predominantly performs these more difficult repairs may have less successful results compared to a surgeon that repairs predominantly smaller tears.[40]

Comparisons of Various Rotator Cuff Surgeries

When comparing the results of the standard open, mini-open, and arthroscopic repair of the rotator cuff it is evident that there are indications for each procedure. Each has inherent benefits and risks related to both the surgical procedure as well as long term results. Complications following rotator cuff surgery have been found to occur in slightly more than 10% of all cases. These complications include failed healing of the tendon repair (6.2 to 15% of all cases), wound infection (1 to 2%), fracture of the acromion or greater tuberosity (0.5%), as well as various other medical complications.[49] The following is a summary of results unique to each procedure.

The standard open rotator cuff repair has traditionally shown satisfactory results. With the advancement of other techniques, the standard open rotator cuff repair is primarily used in large or massive rotator cuff repairs.[30,36] Complications that occur with the standard open repair include long term muscle weakness, denervation of the deltoid, and deltoid retraction.[47]

The mini-open rotator cuff repair is often compared to arthroscopic and open procedures. The mini-open procedure has been shown to be the equivalent of or superior to other procedures.[47] Favorable results with this technique have come with small and moderate sized rotator cuff tears.[38,47,50] Baker and Liu[30] utilized the UCLA End Results Score when comparing the mini-open to the standard open procedure. Eighty-five percent of the patients undergoing the mini-open repair achieved a good to excellent functional level as compared to the patients undergoing the standard open procedure who were identified as achieving a comparable 80% functional level. Note that most large and massive tears are performed with the standard open repair. In addition the patient satisfaction following the mini-open and standard open procedures was 92% vs. 88%, respectively. Baker and Liu[47] reported that there was approximately 1 month earlier return to activity with the mini-open at 4.5 month evaluation.[47]

The results of arthroscopic repair of the rotator cuff are still in the early stages and further long-term studies are required. For patients with a small rotator cuff tear, an arthroscopic repair may be an effective alternative to an open repair.[46] Tippet[47] reported that after 16 months following arthroscopic repair 21 of 29 had satisfactory results based on the UCLA End Results Score. Wolf[47] reported that in 66 arthroscopic repaired patients, 85% demonstrated good to excellent functional results and a patient satisfaction

rate of 92%. The use of arthroscopic repair of the rotator cuff has provided further advancement in the knowledge of rotator cuff disease.

Clinical Factors Affecting Patient Rotator Cuff Outcomes

Regardless of the type of surgery suture management tends to be the most difficult aspect of the arthroscopic repair. These suture techniques require substantial practice to become proficient. The goals of reducing the pain and disabilities remain the same. Various clinical factors, such as onset of injury and surgery, physical therapist and rehabilitation protocol, will effect the outcome of a rotator cuff repair. Acute, or traumatic, injuries of the rotator cuff are usually the result of a single event. Chronic injuries are more difficult to assign a date of injury. Ellman et al[19] report that a repair of a recent massive tear has shown good results, whereas older tears often result in contractures, scarring, and osseous changes that may be difficult or impossible to repair. Patte[40] states, "as soon as a tear of the rotator cuff causes a functional deficit and pain sufficient to require a consultation with a specialist, the shoulder must be examined in detail and the lesion must be precisely classified."[40(p 85)]

As suggested earlier, the rehabilitation protocol will be determined by factors including: patient's age, onset of injury, size of tear, work requirements, desired activity level and motivational level.[38] The expertise of the individual physical therapist will also play into the variation in treatment. Through accurate treatment protocols and critical care pathways some of these variations can be reduced.

One of the advantages of a rotator cuff repair is that pain relief can be expected regardless of the size of tear or type of surgery. Persistent dysfunction of the involved shoulder is a more common occurrence. Preoperative weakness (strength rating of 3 out

of 5 on manual muscle test) in abduction and external rotation was sighted as a potential risk factor for unsatisfactory results. An additional risk factor includes inability to actively abduct the shoulder past 100 degrees preoperatively.[19]

Harryman et al[42] reported that the integrity of the rotator cuff at the 2year follow-up was more indicative of successful results as opposed to the size of the tear at the time of repair. The study stated that, "the repair of a large tear will yield a result comparable with that of repair of a small tear if, again, the cuff remains intact after both operations."[42(p 989)] The study does suggest that the quality of tissue, bone attachment, and potential for a durable repair deteriorate with age and disuse.

The reconstruction of the rotator cuff has the best results following the first repair, as opposed to further attempts at repair.[19,51] Cordasco and Bigliani[35] state that, "Results following surgical management of failed rotator cuff tears are clearly inferior to those obtained in the treatment of the primary repair."[35(p 52)] A procedure may be considered a failure if the patient continues to have pain and disability despite appropriate surgical and rehabilitation efforts. Cordasco and Bigliani[35] suggest that the goal for a revision of the rotator cuff should be pain relief and not necessarily improved function.

The following is a brief overview of factors that can increase the chances for a successful rotator cuff repair:

- Incisions are made in the flexion creases perpendicular to the deltoid fibers
- The deltoid origin is preserved during the surgery
- Adequate anterior acromioplasty is performed to prevent subsequent wear on the tendon
- Involvement of the acromioclavicular joint is evaluated and treated as indicated

- Adhesions are released and rotator cuff tissues are mobilized
- Rehabilitation includes early passive range of motion. Early resisted exercises should be avoided[51]

Commentary on Rotator Cuff Literature Review

A strong and stable shoulder is crucial for many functions of the upper extremity. A shoulder injury may not allow a worker to perform the physical demands of many occupations, especially manual labor. When the dysfunction of a patient's shoulder can threaten his or her livelihood an effective and efficient treatment is demanded.

There is a relative abundance of rotator cuff research material: however, there appears to be a lack of uniformity in rotator cuff evaluation, treatment and functional assessment measures. The research conducted by several authors was referenced throughout various articles. The following authors offer substantial reference material in their respective areas:

Table 1. Various Research Areas Related to Rotator Cuff Pathology and Suggested Authors in these Areas

Research Area	**Authors**
Biomechanics	Clark and Harryman,[42] Soslowsky[17]
Evaluation	Neer[31]
Treatment	Cordasco and Bigliani,[36, 51] Kunkel and Hawkins[30]
Outcome Factors	Hawkins[30]

This review of the literature was intended to provide insights into the differing views of shoulder function and dysfunction. Through continued research and collaboration, more uniformity of measurements and treatments of shoulder dysfunction can be developed and implemented.

In the following chapters (Methodology, Results and Discussion) the outcomes of patients receiving rotator cuff repair and rehabilitation conducted at St. Alexius Medical Center are reported and analyzed. The statistics describe patient profiles of patients having successful and unsuccessful outcomes following standard open rotator cuff repair and rehabilitation.

CHAPTER IV

METHODOLOGY

Subjects of this Study

Sixty-eight rotator cuff repairs (64 patients) performed at St. Alexius/Bone and Joint Center, Bismarck, ND between September 1995 and July 1999 were reviewed retrospectively. One subject was excluded from the study because the patient's physical therapy was not completed at this medical center. Eight other patients were excluded because they underwent rotator cuff repair procedures other than standard open repair with decompression. Only this type of surgery was included in this study. Of the 59 remaining patients, there were 34 males (57.6%) and 25 females (42.4%). The mean age of the patients was 64.3 years, with ages ranging from 38 to 80 years. The median age of patients in this study was 67 years.

This study is a continuation of an ongoing outcome study conducted by St. Alexius Physical Therapy Department, Bismarck, ND in association with The Bone and Joint Center, Bismarck, ND. In 1997 data was collected and published by Jarret Hopstad, MPT[52], to fulfill requirements for the Degree of Master of Physical Therapy from the University of North Dakota. This previous study included 37 rotator cuff repairs (36 patients). Data from these subjects as well as the 31 new subjects (28 patients) are the

database for this study. Evaluations, procedures, treatment protocols, and data collection were similar to this previous study.

All patients included in this study underwent surgical repair of the rotator cuff at The Bone and Joint Center, Bismarck, ND and were referred to St. Alexius Physical Therapy, Bismarck, ND for outpatient physical therapy services. These patients read and signed the consent form for outcome analysis during their initial physical therapy visit (Appendix A). From this pool of outcome data, participants were selected for inclusion in this study if they:

1. Underwent rotator cuff repair by an orthopedic surgeon at St Alexius Medical/Bone and Joint Center, Bismarck, ND.
2. Were referred to St Alexius Physical Therapy Rehabilitation Services.
3. Signed the consent form to be a participant in outcome analysis.
4. Participated in follow-up consultation (after discharge from physical therapy) at 6 months, 1 year, and 2 years post-surgery intervals.

This study was reviewed and accepted by the University of North Dakota Human Subjects Review Board on April 14, 1999 (Appendix B).

Instrumentation

This outcome study, involving the review of patients with rotator cuff repairs, was developed by an internal committee consisting of a physical therapist, an occupational therapist and orthopedic surgeons employed at St. Alexius/Bone and Joint Center, Bismarck, ND. The committee also collaborated with George Davies, MEd, PT, SCS, ATC, CSCS of Lacrosse, Wisconsin a recognized expert in the field of orthopedic physical therapy, to development of the outcome data collection form (Appendix C).

Collection of the data began in early September of 1995. The data collected for this study was documented once during each phase of rehabilitation. Phase 1 occurred between the second to third week post-operatively, phase 2 at week 6, and phase 3 at week 12. Data was also collected at follow-up consultations at 6 months, 1 year, and 2 years following surgery.

The protocol used for the treatment and evaluation of the patients with rotator cuff repairs was developed through collaboration of the physical therapists, occupational therapists, and orthopaedic surgeons. An extensive review of the literature was conducted to develop this protocol. This protocol (Appendix D) was last updated in 1997 and specifies the treatment used for rehabilitation. The outcome form (Appendix C) contained the data gathered by the physical therapists that treated the subjects in this study. Efforts were made to familiarize these individuals with data collection and scoring procedures to promote inter-rater reliability. All rehabilitation procedures performed were standard physical therapy clinical procedures, such as manual muscle testing[53] and range of motion measurements.[54]

Procedures of this Study

The data obtained for this study came from the outcome forms (Appendix C). In a few cases missing data on an outcome form involved rotator cuff tear size and surgical procedure. Certain missing data was obtained from reviews of each subject's operative report. Tear size classifications were defined as follows: tears less than 1 centimeter (cm) in length were classified as small tears, tears 1 to 3 cm were classified as medium size tears and tears greater than 3 cm were classified as large.[30] The surgical procedures performed to repair the rotator cuff involved 3 different types of surgeries. The first

surgical procedure was the standard open repair surgery without subacromial decompression or acromioplasty. The second type of surgery included all open repairs done in combination with an open acromioplasty. The third type of surgery included open repair surgery with arthroscopic decompression. Due to the fact that 88.2% of the subjects (60 of 68 cases) underwent open repair surgery with an open acromioplasty only data from these subjects is reported. The 8 subjects who underwent other surgical procedures were excluded from the study. All data was recorded on data input sheets (Appendix E).

Research Objectives

Research objectives of this study included the identification of:

1. Percentages of patients for which range of motion of the surgically repaired shoulder was comparable to the uninvolved shoulder.
2. Percentages of patients for which muscle strength of the surgically repaired shoulder was comparable with the uninvolved shoulder.
3. Percentages of patients achieving a pain free surgical shoulder using a 0-10 pain scale, where 0 indicated no pain and 10 indicated excruciating pain.
4. Percentages of patients achieving a functional use of the surgically repaired shoulder as recorded by the Upper Extremity Functional Assessment Form.
5. The effects of demographic variables (gender, age, size of tear, etc.) relative to the patients' range of motion, pain level, and functional use of the shoulder.
6. Frequency of visits utilized by patients achieving favorable or unfavorable outcomes.

Because data were recorded at predetermined time intervals this outcomes study did not specify the exact number of visits utilized when the various outcomes goals were achieved. The number of visits was recorded at the time of discharge from physical therapy at the 12 week post-surgical consultation. Functional outcome data was recorded at 12 weeks (phase 3), 6 months, 1 year, and 2 years post-surgery.

Rotator data were analyzed using descriptive statistics computed for all shoulder motions (active and passive), strength levels, and pain levels at each phase of rehabilitation and follow-up evaluations. The Upper Extremity Functional Assessment Form was used to measured the patient's perceived function during Activities of Daily Living (ADLs), such as household duties, outdoor activities, and sporting activities. Data for this questionnaire were collected at one or both of the follow-up evaluations (Appendix C).

A numerical range, 1 through 5, was used to quantify functional levels. A score of 5 indicated that the patient could accomplish the desired task in a "satisfactory" manner (a score of 1 indicated the task was "non-satisfactory"). Scores were only recorded for those activities that pertained to the individual patient's lifestyle, such as household duties, outdoor activities, sports, and other activities of daily living (see Appendix C). The outcome percent scores were computed by dividing the reported functional level by the possible functional level. Criteria used to identify favorable outcomes were selected based upon the criteria used in the prior rotator cuff study.[52] The criteria for this study were as follow:

1. Active forward flexion and active external rotation were selected as important outcomes for the functional use of the shoulder. The parameters used to distinguish favorable outcomes were: (a) active forward flexion of 140 degrees or 75% of the motion of the non-surgical shoulder and (b) active external rotation of 60 degrees or greater or 75% of the motion of the non-surgical shoulder.[54]
2. Favorable strength outcomes were determined by measuring the strength of the external rotators. The clinicians who treated the patients in this study measured strength using the standard "break test" for Manual Muscle Test (MMT) as described by Kendell.[53] The MMT was only utilized at the 12 week consultation based on the Surgical Rotator Cuff Rehabilitation Protocol. After the 12 week consultation the strength of the subjects was tested using a hand held dynamometer. The patients were tested in a standing position with the humerus adducted and the elbow flexed to 90 degrees. A successful outcome required for functional strength necessitated that the patient demonstrate at least a grade 4 (good) rating during MMT or 75% of the strength of the non-surgical shoulder when using a hand held dynamometer to test external rotation.
3. Pain levels of 2 or less were considered favorable results. Pain measurement outcomes were determined by the patients' subjective rating of pain, using a zero value for no pain and a 10 value for excruciating pain.
4. Functional use of the surgically repaired shoulder was considered favorable if the patient reported satisfaction in 75% of the applicable tasks included on the Upper Extremity Functional Assessment Form.

An "excellent" outcome rating was assigned if the subject achieved a favorable rating on 4 out of the 4 outcomes measured (forward flexion, external rotation, strength and pain). A "good" rating was assigned if the subject achieved any 3 of the 4 outcomes. A "fair" rating described those who achieved any 2 of the 4 outcomes. A "poor" rating was recorded for those who only achieved 1 of the 4 desired outcomes. These measures were all collected from the final treatment visit at 12 weeks (the last physical therapy visit before discharge), as well as at the 6 months, 1 year, and/or 2 years post-surgery follow-up evaluations. Only those patients (N=38) who had completed measurements for all 4 of the outcomes were used in data analysis for favorable or unfavorable outcomes.

Statistical Analysis

The data were entered into a computerized program combining the data obtained from this study and the earlier Hopstad Study[52] for the study's statistical analysis. The Statistical Package for the Social Sciences (SPSS) was utilized to formulate the database and analyze the data.[55] As stated before, descriptive statistics for mean, standard deviation, and range values were calculated for the following data and outcomes: number of physical therapy visits utilized by discharge; relative intervals when favorable or unfavorable outcomes were achieved; passive/active range of motion of shoulder forward flexion, external rotation; perceived pain levels; strength of external rotation. Measurements were collected and then analyzed at each phase of rehabilitation.

The ANOVA with Scheffe's Post Hoc analysis was utilized to identify significant differences between consultation phases. Multiple regression was used to identify which demographic variables (age, dominant hand, gender and tear size), if any, had significant influence on the surgical and rehabilitation outcomes. An alpha level of .05 was used for all stated analysis.

Reporting Results

The results of this study will be used to partially fulfill the requirements for the Degree of Masters of Physical Therapy from the University of North Dakota. This study will be published as an independent study report. This study will be made available for the faculty and staff at the University of North Dakota Physical Therapy Department. In addition, the study will be shared with the orthopedic surgeons and physical therapists at St Alexius Medical/Bone and Joint Center, Bismarck, ND and any other interested party from this medical facility as deemed appropriate.

CHAPTER V

RESULTS

Data measurements are reported for shoulder external rotation and forward flexion, strength, and pain for the 59 patients with rotator cuff repairs in this study. Data collected during the 2 to 3 week, 6, and 12 week post-surgical consultations primarily involved measuring and documenting passive shoulder motions and pain levels. Data collected during the 12, 26, 52 and 104 week post-surgical consultations involved documenting active shoulder motion measurements, strength levels, and subjective pain reports. A variation in the number of patients (N) for which data was reported was due to data missing on the Outcome Study Protocol Sheets (Appendix C).

Shoulder strength was measured for external rotation at the 12 week post-surgical rehabilitation consultation using the standard "break test" maneuver during manual muscle testing.[53] At the follow-up 26, 52, and 104 weeks post-surgical consultations external rotation strength at 90 degrees abduction was assessed using a hand-held dynamometer (Microfet). These two ways of assessing strength unfortunately cannot be compared due to the different measurement scales. Tables 2 through 4 report selected clinical findings for physical therapy treatment phases.

Clinical Measurements During Rehabilitation Phases

Table 2. Values for Passive Range of Motion in Degrees and Perceived Pain Level at 2-3, 6 and 12 Weeks Post Surgery

Weeks Post Surgery	*Flexion*				*External Rotation*			
	N	*M*	*SD*	*Range*	*N*	*M*	*SD*	*Range*
2–3	56	100.2	19.9	50.0-151.0	Not Recorded			
6	57	138.7	19.5	89.0-180.0	59	58.0	20.7	10.0-102.0
12	56	152.2	15.0	95.0-175.0	56	74.4	14.2	12.0-110.0

Weeks Post Surgery	*Internal Rotation*				*Perceived Pain Level*			
	N	*M*	*SD*	*Range*	*N*	*M*	*SD*	*Range*
2–3	Not Recorded				53	2.7	1.9	0-7
6	55	54.4	21.2	12.0-150.0	57	1.9	1.9	0-7
12	55	68.1	18.0	34.0-153.0	59	1.4	1.5	0-6

Table 3. Values for Active Range of Motion in Degrees at 12, 26, 52 and 104 Weeks Post-surgery

Weeks Post Surgery	*Flexion*				*Abduction**			
	N	*M*	*SD*	*Range*	*N*	*M*	*SD*	*Range*
12	59	136.8	19.0	85.0-170.0	59	140.4	25.7	72.0-184.0
26	59	139.6	23.5	15.0-172.0	59	150.3	21.2	91.0-191.0
52	59	148.6	13.9	100.0-170.0	59	155.4	17.2	107.0-186.0
104	30	149.3	12.2	125.0-169.0	30	164.53	17.1	112.0-200.0

*Note: active abduction was only measured at week 12 and all follow-up consultations.

Weeks Post Surgery	*External Rotation*				*Internal Rotation*			
	N	*M*	*SD*	*Range*	*N*	*M*	*SD*	*Range*
12	59	68.8	14.4	8.0-110.0	57	56.1	18.0	15.0-89.0
26	59	77.3	14.2	38.0-128.0	59	60.2	15.5	15.0-82.0
52	59	81.3	15.3	37.0-120.0	59	65.4	14.7	20.0-94.0
104	30	83.2	12.8	40.0-110.0	30	63.7	16.0	30.0-91.0

Table 4. Values for Strength and Perceived Pain Levels at 12, 26, 52 and 104 Weeks Post-surgery

Weeks Post Surgery	*Strength Level*				*Perceived Pain Level*			
	N	*M*	*SD*	*Range*	*N*	*M*	*SD*	*Range*
12 *	42	3.8	0.6	2-5	59	1.4	1.5	0-6
26 **	52	17.7	7.7	4.0-36.0	59	0.8	1.2	0-5
52 **	49	20.4	7.9	4.0-35.0	59	0.6	1.0	0-4
104 **	24	25.0	10.7	4.0-22.0	28	0.4	1.0	0-4

* Indicates that external rotation strength was tested with a MMT
** Indicates that external rotation strength was tested with a hand-held dynamometer (Microfet)

Tables 2 through 4 indicate that patients with surgically repaired rotator cuff tears demonstrate consistent improvements overtime in mean active and passive range of motion, strength, and perceived pain levels. The data also indicated that clinical improvements were achieved after discharge from direct physical therapy treatment. The only exception to this improvement was a minor decrease in active internal rotation between 52 and 104 weeks (65.4 to 63.7 degrees). This decrease is within values for possible measurement error.

Patient Demographic Variables: Tear Sizes, Age and Gender

During the surgical procedure the physicians classified rotator cuff tears as small (less than 1 cm), moderate (1 to 3 cm), large (3 to 5 cm), and massive (larger than 5 cm) utilizing the Kunkel and Hawkins classification system.[30] Of the 56 patients with reported tear sizes 53.6% were large (N = 30), 21.4% (N = 12) were medium and 25.0% were small (N = 14). Table 5 summarizes the comparison of tear size to age and gender in this study.

Table 5. Crosstabulation between Tear Size, Age Group and Gender for N = 59 patients

Demographics	*Total per Group*	*Small Tear*	*Medium Tear*	*Large Tear*
Age				
<65 Years	25	5	6	13
≥65 Years	34	9	6	17
Gender				
Male	34	6	5	21
Female	25	8	7	9
Total per Tear Size		14	12	30

Table 5 provides information concerning the age and gender of the patients involved in this study. The incidence of large rotator cuff tears accounted for over one-half of the cases. In addition, large tears were the most prevalent size tears for patients both under and over 65 years of age. Large tears were prevalent in 70% of males compared to 30% females.

Comparing Favorable and Unfavorable Outcomes

In Chapter 4, Methodology, the patient criterion for patients achieving favorable outcomes for range of motion, strength, and perceived pain were specified. The overall outcomes of rotator cuff repair and rehabilitation are summarized in Table 6. Data is available for 38 patients on the Composite Outcome Scores.

Table 6. Overall Outcomes for Surgical Rotator Cuff Repair and Rehabilitation

Overall Outcomes	*N at 12 Weeks*	*N at 26 Weeks*	*N at 52 Weeks*	*N at 104 Weeks*
Excellent (4 of 4 outcomes achieved)	20	23	34	9
Good (3 of 4 outcomes achieved)	10	12	24	1
Fair (2 of 4 outcomes achieved)	4	3	8	
Poor (1 of 4 outcomes achieved)	4		2	
Total	38	38	34	10

At the 12 week consultation, the end of formal therapy, 38 patients had data reported in all 4 outcomes measures including active range of motion for external rotation, forward flexion,[54] strength,[53] and pain levels.[18] Of those 38 patients 79.0% achieved good to excellent outcomes. When focusing on individual components, 85% of the patients achieved favorable external rotation outcomes. Eighty percent of the patients achieved favorable forward flexion outcomes. Seventy-seven percent of the patients who had their strength tested at the 12 week consultation exhibited strength levels of at least a 4 (good) grade during manual muscle test of external rotation.[53] Eighty percent of the patients achieved a subjective pain rating of 2 or less, on a 0 to 10 scale. The mean number of outpatient visits required for rehabilitation for patients with favorable outcomes was 6.8 with a standard deviation of 1.9.

Table 7 includes the number of visits completed at the time a favorable outcome was achieved. Descriptive data regarding the number of visits utilized are presented in relation to favorable, unfavorable and total outcomes. The mean number of visits was higher for those patients who failed to reach desired outcome levels compared to those achieving desired outcome levels.

Table 7. Physical Therapy Visits Utilized by Discharge at 12 Weeks

Subjects	Individual Components								Composite of Individual components	
	Active External Rotation		Active Flexion		Strength		Pain			
	n	M±s	n	M±s	n	M±s	n	M±s	n	M±s
Patients with Favorable Outcomes (Composite Score ≥3)	42	7.5±3.2	39	7.3±2.9	36	7.0±2.2	47	7.5±1.9	30	6.8±1.9
Patients with Unfavorable Outcomes (Composite Score <3)	7	8.7±4.8	10	9.6±4.8	11	6.8±2.2	12	7.3±2.0	8	8.0±3.5
Total Reporting Data									38	7.7±3.3

The individual components that show the greatest difference in number of visits utilized were active external rotation and flexion. Patients with favorable active flexion utilized 7.3 visits compared to patients with unfavorable outcomes who utilized 9.6 visits. Patients with favorable active external rotation outcomes utilized 7.5 visits compared to patients with unfavorable outcomes who utilized 8.7 visits. Certain factors could affect the number of physical therapy visits utilized, such as patient progression, patient motivation, therapist experience, patient-therapist relationship, patient infections, scheduling ease or difficulty, and patient compliance to name a few.

Perceived Level of Overall Function

The Upper Extremity Functional Assessment Form (Appendix C) measured the patients' perceived level of overall function. This questionnaire was completed at the 26, 52 and 104 week post-surgical consultations. Patients were considered to have achieved

favorable upper extremity function if they reported satisfactory levels of performance for 75% of the possible functions.

At the 26 weeks consultation 27 patients reported a mean perceived functional level of 88.0% with a standard deviation of 9.5 (see Methodology Chapter for calculation procedure). At the 52 weeks consultation 39 patients reported a mean perceived functional level of 94.8% with a standard deviation of 7.7. The perceived functional level percentage increased even further between 52 weeks consultation and the 104 weeks consultation when 21 patients reported a mean functional level of 97.3% with a standard deviation of 3.7. The patient's perceived functional outcome levels are reported in Figure 5.

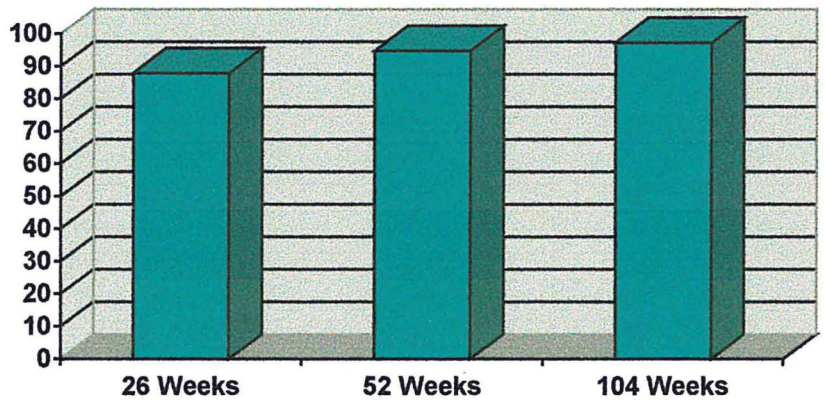

Figure 5. Results of Upper Extremity Functional Assessment by mean percentages as reported during follow-up consultations.

Figure 5 indicates that patients continued to improve in function following discharge from formal physical therapy treatment. Interestingly, there was a greater improvement between 26 weeks and 52 weeks (88.0% to 94.8%) then between 52 weeks and 104 weeks (94.8 % to 97.3%).

It should be noted that the Surgical Rotator Cuff Protocol (Appendix D) initiated gentle resistive exercise for individual rotator cuff muscles at 8 to 12 weeks post-surgery. Discharge from formal physical therapy occurred at 12 weeks. All patients were instructed in independent home exercise programs; however, it is difficult to determine patient compliance. It was most appropriate, therefore, to analyze upper extremity functional at 26, 52, and 104 week consultations. The patients would have had an opportunity to utilize their surgically repaired shoulder with a wide variety of functional activities over a substantial time span.

Multiple Regression Analysis

Multiple regression analyses were conducted to identify the effects of demographic factors (age, tear size, gender and dominant hand) on patient outcomes. The outcomes measured were the degrees of shoulder external rotation, the levels of perceived pain, and the numbers of physical therapy visits utilized. Multiple regression analysis at alpha = .05 indicated that age, tear size, gender or hand dominance did not significantly predict clinical or perceived functional outcomes of the patients in this study at any phase of rehabilitation or follow-up consultation.

Patient Outcome Profiles

The data collected from this study was utilized to compile a patient profile for patients who achieved either favorable or unfavorable results. Overall favorable outcome results were designated if a patient achieved 3 or more favorable outcome scores (see Table 7). Unfavorable outcome results were designated if a patient achieved less than 3 favorable outcome scores (see Table 7). Table 8 describes the frequencies of various patient demographics associated with either favorable or unfavorable outcomes.

Table 8. Frequency of Demographic Factors Associated with Favorable or Unfavorable Patient Outcomes

Profiles	*Patients*	*Gender*		*Tear*			*Age*	*Dominant Hand*		*Visits*
		M	*F*	*S*	*M*	*L*	*M (SD)*	*Inv.*	*Noninv.*	*M (SD)*
Favorable Outcomes	30	16	14	5	9	14	65.5 (9.2)	11	11	6.8 (1.9)
Unfavorable Outcomes	8	6	2	2	3	2	63.4 (12.5)	2	1	8.0 (3.5)
Total	38	22	16	7	12	16	64.3 (9.6)	13	12	7.7 (3.3)

Table 8 included demographic variations for patients who achieved favorable or unfavorable outcomes. Of the 38 patients included in Table 8, 79% of patients achieved favorable outcomes. As indicated previously, demographic factors including gender, age and dominant hand involvement did not have significant influences on the patients' outcomes. Gender demographics (male/female) outcomes were relatively equal for patients achieving favorable outcomes. Of those patients who achieved favorable outcomes 50% were classified as with large rotator cuff tears. Forty-three percent of those patients who achieved unfavorable outcomes were classified as having medium rotator cuff tears. The frequency of patients having their dominant arm being surgically involved was relatively equal for those patients achieving favorable or unfavorable outcomes. Patients achieving unfavorable outcomes utilized increased physical therapy visits.

CHAPTER VI

DISCUSSION

This study was conducted to identify patient progression and patient outcomes. Data analysis can offer healthcare providers necessary feedback for treatment protocol development and refinement. By reviewing patient outcome profiles healthcare professionals can better provide treatments of patients having similar profiles.

The physical therapy profession is presently utilizing the *1997 Guide to Physical Therapy Practice*[45] as a tool for taking a proactive stand towards improving the present state of health care. One of the most debated topics included in the *1997 Guide to Physical Therapy Practice*[45] is the expected number of visits per episode of care. The 1997 Guide describes four practice patterns for classifications of rotator cuff syndromes. The selected classification for the patients in this study is Pattern 4J: Impaired Joint Mobility, Motor Function, Muscle Performance, and Range of Motion Associated with Bony or Soft Tissue Surgical Procedures. The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Code for these patients is 726.1. The *1997 Guide to Physical Therapy Practice*[45] includes suggested examination, intervention, and discharge criteria based on the Preferred Practice Patterns. The guide states that the range of expected physical therapy visits varies from a low of 6 visits to as high as 87

visits. The Guide's maximum of the range (87 visits) allows for the possibility of patients with slower healing progression or other complications.

Analysis of the data in this study identified the relative number of physical therapy visits utilized by patients who achieved favorable, as well as unfavorable rotator cuff functional outcomes. In this study the mean number of outpatient visits for those with favorable outcomes was 6.8 with a standard deviation of 1.9 and a range from 3 to 20. The mean number of outpatient visits for those with unfavorable outcomes was 8 with a standard deviation of 3.5 and a range from 5 to 17. In comparison to the guide's range of expected physical therapy visits (6 to 87), both the patients having favorable and unfavorable outcomes were at the lower end of the range. This lower range indicates that those patients with unfavorable outcomes could have been treated in additional physical therapy visits and still been within the Guide's recommendations.

Comparing Protocol Goals and Patient Outcomes

The following discussion includes a comparison of the predetermined Surgical Rotator Cuff Protocol Goals (Appendix D) and the patient outcomes from this study. The phases of rehabilitation do not identically match the predetermined times of consultation. Thus, the goals of rehabilitation are compared to the phase at which the goal was achieved.

Overall Goals of Rehabilitation:
12 week rehabilitation program

Goal: Painless shoulder ≤ 2 on a 0-10 pain scale.

Patients Achievement: From the 6 weeks consultation throughout each phase of the study the mean perceived pain level of the patients in this study was below 2 on the 0 to 10 pain scale.

Goal: Minimum functional shoulder active range of motion: flexion to 100 degrees, abduction to 90 degrees, external rotation to 45 degrees by the end of the third month.

Patient Achievement: From the 12 weeks consultation throughout each phase of the study the patients achieved the minimum functional goals for active range of motion. At 12 weeks the mean for flexion was 136.8 degrees with a standard deviation of 19.0, abduction was 140.4 degrees with a standard deviation of 25.7, and external rotation was 68.8 degrees with a standard deviation of 14.4. All patients exceeded the minimum functional goals.

Goal: Functional strength returns (external rotation has a 25% or less deficit compared to the uninvolved side).

Patient Achievement: The patients in this study achieved a mean external rotation strength deficit of 17.3% at 26 weeks, 6.7% at 52 weeks and 5.5% at 104 weeks. Patients achieved a higher level of function than stated in the original goal.

Phase 1: 0 to 3 Weeks Postoperative

Goal: Increase range of motion to 90 degrees of passive flexion.

Patient Achievement: At 2 to 3 weeks the mean passive flexion was 100.2 with a standard deviation of 19.9.

Phase 2: 3-4 to 8 Weeks Postoperative

Goal: At 6-8 weeks, increase active assisted/active flexion to 90 degrees.

Patient Achievement: At 6 weeks the mean passive flexion was 138.7 with a standard deviation of 19.5. This goal could not be completely addressed due to the fact that active range of motion was not reported until 12 weeks.

Phase 3: 8 to 12 Weeks Postoperative

Goal: Full PROM by 9 weeks postoperatively: 140-160 degrees flexion; 70-80 degrees external rotation at 90 degrees abduction.

Patient Achievement: At the 12 weeks consultation the patients achieved a mean passive flexion of 152.2 with a standard deviation of 15.0 and external rotation of 74.4 with a standard deviation of 14.2. These values meet the protocol goals.

Phase 4: 12-16 Weeks Postoperative

Goal: Initiate resisted abduction beyond 70 degrees as well as elevation beyond 90 degrees once external rotation is 25% or less deficit compared to the uninvolved side.

Patient Achievement: At the 12 weeks consultation the patients achieved a mean external rotation strength deficit of 17.3% compared to the uninvolved side.

The patients in this study exceeded the overall goals of rehabilitation of the Surgical Rotator Cuff Protocol utilized by St Alexius/Bone and Joint Center. At each phase of rehabilitation the protocol goals for pain, range of motion, and strength were met or exceeded. This achievement indicates that St Alexius/Bone and Joint Center is realizing the rehabilitation goals they have established for patients having a standard open repair of the rotator cuff.

Outcomes studies, such as this study, can offer support in specifying and justifying standards for rehabilitation services. Chapter V (Results) offers quantitative descriptions related to the number of physical therapy visits utilized. The additional utilization of physical therapy services by patients having unfavorable outcomes may indicate that these patients were not adequately progressing through treatments to achieve their goals. The physical therapist may also have been attempting to facilitate patient progression through increased physical therapy visits.

A multiple regression analysis indicated that age, tear size, gender and dominant hand demographics did not significantly influence patient outcomes. Such demographics did not promote or inhibit favorable or unfavorable outcomes. Perhaps a study with a larger database may identify certain demographic factors that may be more predictive of patient outcomes.

It is difficult to compare results from this rotator cuff repair study to other studies due to a lack of uniformity in tear classifications and functional outcome measurements. A 1997 study by Kronberg et al[56], however, shares many other similarities with this study. These researchers reviewed 37 patients up to 2 years following acromioplasty and repair of a full-thickness rotator cuff tear. Their findings indicated that 80% of the patients had only mild disability following rotator cuff repair. The patients had achieved acceptable functions of their repaired shoulder; however, they did demonstrate slight deficits in range of motion and strength compared to the uninvolved shoulder. In comparison to the Kronberg et al[56] study, the outcome data from this study were similar. The study conducted through St Alexius/Bone and Joint Center indicated that at 2 years post-surgery there was less than a 5% difference between the involved and noninvolved

shoulder for mean active flexion (4%), active external rotation (3%), strength (Microfet) (2%), and perceived function (3%).

Due to the fact that 57.6% of the patients in this study were 65 years or older it may be more reasonable to make comparisons between the involved and noninvolved measurements rather than comparing clinical measurements to "normal" expected values. For instance, the normative value for forward shoulder flexion is 180 degrees.[54] In this study the mean for flexion at the 104 weeks consultation was 149.3 with a standard deviation of 12.2. This mean was more than 30 degrees less than the "normal" expected value of 180 degrees. Interestingly, the mean difference between the involved and noninvolved shoulder for mean active flexion was only 4%.

Limitations of the Study

The reliability of data collection in the medical profession, including physical therapy, has been hampered by a lack of uniformity in recording clinical measurements. Outcomes research should utilize data collection techniques that have been universally accepted by a majority of the medical profession and which recognize patient variability in responses.[1, 8] Lack of universal standardization in classifying rotator cuff tear sizes limits "exact" comparisons with other studies using different classification systems.

This study lacked standardization of measurement of strength. At 12 weeks post-surgery strength was measured with the use of a manual muscle test whereas at other subsequent phases a hand held dynamometer or manual muscle test was used to assess strength. Consequently, comparisons between 12 weeks and follow-up consultations were not possible.

Another possible limitation of this study was the fact that data was collected at predetermined phases regardless of an individual patient's improvements. For example, a majority of data was collected during the 12 weeks post-surgery consultation. Subjects may have achieved a favorable outcome at times before this consultation period.

Data collection was also limited due to missing information on the outcome forms. The physical therapists involved in the study may have neglected to record all pertinent data due to the repetitive nature or length of the form. An effective outcome study requires periodic follow-up reviews of the outcome forms involving input from researchers, clinicians, experts in the field and any other pertinent individuals. The form should be evaluated to ensure that future forms are concise yet include all desired data to develop a valid database (Appendix C).

Many third party payers are utilizing patient satisfaction data for assessing outcomes of medical treatment. Patient satisfaction data would providing insight as to how well healthcare is treating the patient as a "whole". This study utilized the Upper Extremity Functional Assessment Form (Appendix C). In an effort to improve this outcome study, it is recommended that be this questionnaire be evaluated for reliability and validity.

Future investigations could utilize a clinometric to objectively assess function at various phases of rehabilitation. There are a variety of measurement tools such as the Simple Shoulder Test (SST), the Constant Shoulder Score, and the University of California at Los Angeles (UCLA) End-Result Score. Each of these tools have unique advantages and disadvantages inherent in their design.[57] The UCLA End-Results Score was utilized in numerous research articles.[19, 30, 39, 47, 57] This test consists of ratings of

pain levels, function, active forward flexion, strength in forward flexion, and patient satisfaction. The UCLA End-Results Score; however, has been criticized for the subjectivity of the manual strength testing.[57] The advantages of standardized tests for this outcomes study would be increased validity and comparability to similar outcomes studies. The use of a clinometric may improved the research methodology and outcome measurements of this study.

Further Suggestions for Improvements to this Study

A review of the St Alexius/Bone and Joint Center Surgical Rotator Cuff Protocol (Appendix D) reveals that this protocol progresses through specified phases at 0 to 3 weeks, 3 to 8 weeks, 8 to 12 weeks, 12 to 16 weeks, and 16 weeks to discharge. In comparison, the Patient Data Collection Sheets for this outcomes study progress from the second to third week, 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery. Having similar phases of rehabilitation protocol consultations would have eased patient data collection phases.

Suggestions for Further Research

The following suggestions are offered for other descriptive, longitudinal, or comparative outcomes research studies:

1. Conduct functional outcomes studies focusing on other post-surgical conditions treated by physical therapy.
2. Investigate specific physical therapy treatments involved in patients achieving or not achieving protocol goals. These studies can aid in accounting for patient improvements due to placebo effects, spontaneous recoveries, or co-intervention results. These studies may include analysis of isokinetic testing.

3. Analyze functional outcomes following various rotator cuff repair surgeries including acromioplasty without repair, mini-open repair, and arthroscopic repair.
4. Investigate the functional outcomes of patients injured in various athletic activities and training programs.
5. Compare functional outcomes through radiographic data analysis at various phases of rehabilitation.
6. Analyze the use and effectiveness of various classification systems for rotator cuff tear sizes.
7. Continue this type of rotator cuff repair outcomes study to increase the patient database and thereby increasing the usefulness of the statistical analysis.

CHAPTER VII

CONCLUSION

The quest to provide quality patient care, as well as the demand for healthcare accountability, are ongoing challenges of outcome research. In its most simplistic form, the definition of an outcome is the end-result of the treatment and the effectiveness of care.[6] Keller describes quality with the following equation, "Quality = Efficiency + Effectiveness + Appropriateness."[5(p 488)] Outcomes research has evolved to provide both clinical quantitative analysis as well as patient focused data.[13] By reviewing past patient outcomes, healthcare professionals can better prepare for future treatments of patients with similar profiles. Analyzing patient outcomes following rotator cuff repair will help shape future medical practice patterns.

A thorough knowledge of the shoulder anatomy and biomechanics is essential when investigating outcomes of a rotator cuff repair. The rotator cuff, also referred to as the SITS muscles, is composed of the Supraspinatus, the Infraspinatus, the Teres Minor, and the Subscapularis. The rotator cuff offers dynamic stability from which the rest of the upper extremity is allowed to perform more intricate activities.[15] In addition to the structures and functions of the shoulder girdle and rotator cuff, the topics of dysfunction, evaluation, and treatment must be considered.

Rotator cuff pathology is associated with multifactorial causes including extrinsic factors, such as morphology of the coracoacromial arch, overload, repetitive use, and kinematic abnormalities. Intrinsic factors such as vascular supply to the tendon and orientation of tissue fibers also contribute to rotator cuff pathology.[17] It is difficult to isolate one contributing factor; therefore, the combination of these factors should be analyzed.

From the rotator cuff repair data reported by the St. Alexius/Bone and Joint Center this descriptive outcomes study was developed. Fifty-nine patients' rotator cuff repairs were selected for the study. Thirty-four males and 25 females were included in the study. The mean age of the patients was 64.32 years, ranging from 38 to 80 years, with a median age of 67 years. Patients demographics included rotator cuff tear sizes: 14 small, 15 medium, and 31 large. The dominant shoulder was surgically involved in 52.20% of the patients who achieved favorable outcomes. In comparison, the dominant shoulder was surgically involved in 33.30% of the patients who achieved unfavorable outcomes.

Patients were discharged from formal physical therapy treatment at 12 weeks post-surgery. The following describes the research objectives and related outcomes of this study at 12 weeks post-surgery.

1. Percentages for which range of motion of the surgically repaired shoulder was comparable to the uninvolved shoulder.

Seventy-nine percent of the subjects achieved favorable outcomes for external rotation. Eighty-six percent of the subjects achieved favorable outcomes for forward flexion. The mean number of physical therapy visits for those patients with favorable outcomes was 7.5 visits for external rotation and 7.3 visits for flexion. The mean number

of physical therapy visits for those patients with unfavorable outcomes was 8.7 visits for external rotation and 9.6 visits for flexion.

2. Percentage of patients for which muscle strength of the surgically repaired shoulder was comparable with the uninvolved shoulder.

Nearly 77 % of the subjects who had their strength tested at phase 3 exhibited strength levels of at least a grade 4 (good) out of 5 on the manual muscle test. The mean number of physical therapy visits utilized by these patients was 7 visits. Interestingly, those patients with unfavorable outcomes utilized a mean 6.8 physical therapy visits.

3. Percentage of patients achieving a pain free surgical shoulder using a 0-10 pain scale, where 0 indicated no pain and 10 indicated excruciating pain.

A subjective pain rating of 2 or less, on a 0-10 scale, was realized by 80% of the patients. The number of physical therapy visits utilized by these patients was a mean of 7.5 visits. Those patients with unfavorable outcomes utilized a mean of 7.3 visits.

4. Percentage of patients perceived level of overall function as recorded by the Upper Extremity Functional Assessment Form at 26, 52, and 104 weeks post-surgery.

At the 26 weeks consultation the mean perceived functional level was 88.0%. At the 52 weeks consultation the mean perceived functional level was 94.8% with a standard deviation of 7.7. The perceived functional level percentage increased even further between 52 weeks consultation and the 104 weeks consultation to a mean perceived functional level percentage of 97.3%.

5. Demographic variables (gender, age, size of tear, etc.) reported in relation to the patients' range of motion, functional use of the shoulder, and pain.

Multiple regression analysis with alpha .05 indicated that age, tear size, gender and dominant hand did not have significant prediction value for the clinical or perceived functional outcomes of the patients involved in this study.

6. The frequency of visits utilized by patients achieving favorable or unfavorable outcomes.

The mean number of outpatient visits of all patients in the study was a mean of 7.66. The number of physical therapy visits utilized by patients with favorable outcomes 6.8 visits. Those patients with unfavorable outcomes utilized a mean of 8.0 visits.

Data from this study will be utilized to provide rotator cuff repair and rehabilitation information to St. Alexius/Bone and Joint Center, third party payers, the University of North Dakota Physical Therapy Department, and interested patients. St. Alexius/Bone and Joint Center will be provided with quantitative data to analyze rotator cuff surgical and rehabilitation outcomes. Health care providers will have data to evaluate patient care and performance as they strive toward continued quality improvement. The University of North Dakota Physical Therapy Department will benefit through further advancement of surgical and rehabilitation research and reference material. Most importantly, future patients will benefit from more functionally effective and cost efficient rotator cuff treatments.

APPENDIX A

ST. ALEXIUS MEDICAL CENTER

"Let all be received as Christ"

LONGITUDINAL STUDY CONSENT FORM

THE RESULTS OF YOUR REHABILITATION PROCESS ARE BEING GATHERED AS PART OF A LONG TERM STUDY OF SURGICAL AND FUNCTIONAL OUTCOMES OF YOUR PARTICULAR DIAGNOSIS. ONCE YOU HAVE COMPLETED YOUR FORMALIZED PHYSICAL THERAPY TREATMENT AND HAVE BEEN DISCHARGED FROM ST. ALEXIUS MEDICAL CENTER, WE WOULD APPRECIATE THE OPPORTUNITY OF RETESTING YOUR STATUS AT 6 MONTHS, 12 MONTHS, AND 24 MONTHS POST DISCHARGE. THESE LAST THREE VISITS WOULD BE FREE OF CHARGE AND ALL RESULTS WOULD BE MADE READILY AVAILABLE TO YOU.

WHEN UNDERGOING THESE TESTS, THERE ARE CERTAIN INHERENT RISKS WHICH INCLUDE THE POSSIBILITY OF MUSCLE AND LIGAMENTOUS INJURY. YOU SHOULD EXERT YOUR BEST EFFORT THROUGHOUT THE EVALUATION BUT AT NO TIME ARE YOU EXPECTED TO EXPERIENCE ANY INCREASE IN PAIN OR DISCOMFORT BEYOND A LEVEL YOU FEEL YOU CAN COMFORTABLY TOLERATE. AT NO TIME WILL YOU BE FORCED TO PERFORM ANY TESTS WHICH YOU DO NOT WISH TO PERFORM AS YOU ARE IN CONTROL OF THE TESTING AND MAY STOP WHENEVER YOU FEEL THAT YOU SHOULD NOT PROCEED. IF WE SEE YOU EXERTING EFFORTS, WHICH IN OUR OPINION MAY PLACE YOU IN DANGER, WE WILL STOP YOU.

BASED ON THE ABOVE INFORMATION THAT I HAVE READ AND UNDERSTAND, I AGREE TO PARTICIPATE IN THIS LONGITUDINAL STUDY.

_____

DATE

_____

PARTICIPANT SIGNATURE

900 East Broadway Box 5510
Bismarck, North Dakota 58502-5510
701-224-7000
FAX 701-224-7284
TDD 701-224-7946

APPENDIX B

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW

University of North Dakota Institutional Review Board

DATE: April 7, 1999 PROJECT NUMBER: IRB-9904-210

NAME: David Joseph Kohns , DEPARTMENT/COLLEGE: Physical Therapy

PROJECT TITLE: The Functional Outcome of an Accelerated Protocol on Patients Receiving a Rotator Cuff Repair

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on April 14, 1999 and the following action was taken:

☐ Project approved. EXPEDITED REVIEW NO. _____.
Next scheduled review is on _____.

☑ Project approved. EXEMPT CATEGORY NO. 4. No periodic review scheduled unless so stated in the Remarks Section.

☐ Project approved PENDING receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. **This study may NOT be started UNTIL final IRB approval has been received**. (See Remarks Section for further information.)

☐ Project approval **deferred. This study may not be started until final IRB approval has been received**. (See Remarks Section for further information.)

☐ Project **denied.** (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

PLEASE NOTE: **Requested revisions for student proposals MUST include adviser's signature.**

cc: R. Mabey, Adviser

Signature of Designated IRB Member
UND's Institutional Review Board

4-14-99
Date

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

___EXPEDITED REVIEW REQUESTED UNDER ITEM ___ (NUMBER[S]) OF HHS REGULATIONS
_X_EXEMPT REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR: David Joseph Kohns **TELEPHONE:** (218) 773-8634 **DATE:** 3-34-99
ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: UND Physical Therapy Department P.O. Box 9037 Grand Forks, ND 58202-9037 (701) 777-2831

SCHOOL/COLLEGE: University of North Dakota **DEPARTMENT:** Physical Therapy **PROPOSED PROJECT DATES:** 2-15-99 to 5-15-99

PROJECT TITLE: The Functional Outcome of an Accelerated Protocol on Patients Receiving a Rotator Cuff Repair.

FUNDING AGENCIES (IF APPLICABLE): Not Applicable
TYPE OF PROJECT (Check ALL that apply):

___ NEW PROJECT _X_ CONTINUATION ___ RENEWAL ___ DISSERTATION OR THESIS RESEARCH _X_ STUDENT RESEARCH PROJECT

___ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Renee Mabey

PROPOSED PROJECT: ___INVOLVES NEW DRUGS (IND) _____ INVOLVES NON-APPROVES USE OF DRUG _X_ INVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):

___ MINORS (<18 YEARS) ___ PREGNANT WOMEN ___ MENTALLY DISABLED ___ FETUSES ___ MENTALLY RETARDEC

___ PRISONERS ___ ABORTUSES ___ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE

IF YOUR PROJECT HAS BEEN\WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S),PLEASE LIST NAME OF BOARD(S):
Status: ___ Submitted; Date _____ ___ Approved; Date_____ _____Pending

1. **ABSTRACT:** (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.

Health care reforms have been apparent to both customers and providers of care. As within all service industries, health care professionals are accountable for the quality of the service they provide. Health care professionals must be accountable to their patients, insurance providers and profession. The term Continuous Quality Improvement (CQI) has recently been a focus of the health care community. Physical therapy is utilized in a wide variety of conditions. Many of the treatments used in physical therapy lack standardization or conclusive validation. Functional outcome data for physical therapy treatment can provide the accountability this profession requires to adapt to the ever-changing world of health care.

This project is a continuation of a retrospective review of data collected from voluntary and confidential patients at St. Alexius Medical

Center in Bismarck, ND. Each subject underwent shoulder rotator cuff surgical repair. Specific functional tests were performed on the subjects to assess functional improvements at various time intervals during their rehabilitation programs. Descriptive statistics and multiple regression procedures will be utilized to analyze and interpret the outcome data. Results of this study will be use in further establishing quality standards of care and accountability of shoulder rotator cuff rehabilitation.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. **PROTOCOL:** (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Purpose:
The purpose of this study is to determine the functional outcomes of patients who have undergone physical therapy treatment following rotator cuff surgical repair. The outcome data analyzed will include: range of motion, muscle strength, pain level, and functional use of surgically repaired shoulder. An additional analysis will be conducted on the effects of various demographical variables (gender, age, size of tear, etc…) on the outcome data. The data will be collected at predetermined intervals up to two years post operatively.

Subjects:
Participants included in the study were patients who underwent optional surgical repair of the rotator cuff at St. Alexius Medical Center. The patients willingly participated in the study and understood that there was no difference in treatment programs or penalty for withdrawing from the study. These patients read and signed the consent form for outcome analysis during their initial physical therapy evaluation. A parent, or guardian, signed approval for any minors that participated in the study. Outcome data was collected by St Alexius physical therapist from August 15, 1997 to August 15, 1999 on a standardized form. Subjects were selected for analysis by meeting the following criteria:

1. Underwent rotator cuff repair by an orthopedic surgeon in the Bismarck area.
2. Referred to St. Alexius/Bone and Joint Center for physical therapy services.
3. Signed consent form to be a participant in outcome analysis (Attachment A).
4. Completed all outcome evaluations at three weeks, six weeks, six months, one year and two years post-operatively (Attachment B).

Procedure and Instrumentation:
The procedure will entail comparing outcome forms with their respective operative reports of participants who met the criteria for analysis since the last data collection, August 15, 1997. New data will be compiled with all previous data to analyze and to interpret results for the subjects selected in the initial and subsequential patient sample. A standardized data sheet completed by St. Alexius Medical Center (Attachment B).

Functional outcomes were defined as the:

1. Number of physical therapy visits required until range of motion of th surgically repaired shoulder is comparable to the uninvolved shoulder. Number of visits required until muscle strength of the surgically repaired shoulder is comparable with the uninvolved shoulder.
3. Number of visits required to achieve functional use of the surgically repaired shoulder as recorded by the Upper Extremity Functional Assessment Form (Jung, 1995).
4. Number of visits required to achieve a pain free surgical shoulder using a 0-10 pain scale, where 0 indicates no pain and 10 indicates excruciating pain.
5. Influence of demographic variables(gender, age, size of tear, etc...) on the range of motion, functional use of the shoulder, and the pain level at three weeks, six weeks, six months, one year and two years post-operatively.

Analysis:
Outcomes 1-4 will be investigated using descriptive statistics for measure of central tendency and variance. Multiple regression procedures will be used to examine outcome 5. All data will be collected and analyzed in a codified format to insure participant confidentiality

3. **BENEFITS:** (Describe the benefits to the individual or society.)

The benefits of an outcome study are to determine the most effective and efficient way to achieve a desired goal. Improvements in the quality of medical service will ultimately result from this analysis. Data from this study will benefit third party payers (insurance companies, Workers Compensation, Medicare/Medicaid, etc.) who provide reimbursement for health care services. These groups will receive improved services for their investment. St. Alexius Medical Center will be provided with quantitative data to analyze rotator cuff surgical and rehabilitation results. Individual health care providers will have feedback to evaluate their performance as they work toward continued quality improvement. Most importantly, future patients will benefit from a more functionally effective and cost efficient treatment. The data from this study will be made available to St. Alexius Medical Center, the University of North Dakota Physical Therapy Department and the Health Science Library as a future reference for rotator cuff rehabilitation and outcome studies. Outcome studies are a valuable research technique whereby physical therapy can justify and self-govern their profession. The future of health care demands that each component must be accountable for the effectiveness and efficiency of their service.

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psycho-logical, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

Collection of the data by St. Alexius Medical Center was done during the course of standard patient care involving no extraordinary risk to the patient. Risks for the patient as a result of analysis of the data include confidentiality, which will be maintained as no individual names, or identification will be used. The results of this study will be reported in

an aggregate grouping of subject codes that will be used to input data. St. Alexius Medical Center will maintain the original forms and Joint Center and copies will be kept in the Physical Therapy Department for a period of two years.

5. **CONSENT FORM:** A copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, documen the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

Consent forms for inclusion in this outcome study were gathered by St. Alexius/Bone and Joint Center and are maintained in their facility. A parent, or guardian, signed approval for any minors that participated in the study. No additional consent forms will be utilized for this patient chart review. A copy of the consent form is included in attachment A.

6. For **FULL IRB REVIEW** forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator	Date
Project Director or Student Adviser	Date
Training or Center Grant Director	Date

(Revised 3/1996)

APPENDIX C

Human Performance Center
St. Alexius Medical Center

Sports Medicine

Physical Therapy

Exercise Physiology

Frappier Acceleration

Hand Therapy

Cardiac Rehabilitation

LONGITUDINAL OUTCOME STUDIES

A longitudinal outcome study was set up for a variety of diagnoses, specifically surgical procedures September 1, 1995 by St. Alexius Medical Center and the Institute of Sports Medicine. Outcomes, specific to physical therapy, have been set up to be followed up for two years post surgery. The studies monitored will include those individuals who have undergone the following surgical procedures: Achilles tendon repair, ACL reconstruction, Bankart repair, biceps tendon repair, Brostrom reconstruction, capsular shift, patellofemoral joint surgery, as well as rotator cuff repair. All subjects are notified of the study and will have a consent form filled out specifically when they go beyond the normal insurance reimbursable time table. Please note that under no circumstances, subjects will be exposed to any procedure or test which is beyond the normal protocol.

Data compiled with the outcome studies will be kept within the Institute of Sports Medicine as well as original copies of specific tests during the normal rehab kept within the medical records department at St. Alexius Medical Center. The Bone & Joint Center will also be offering assistance in terms of the actual surgical procedures.

This letter is to notify those institutions which will be assisting in helping to compile this outcome data that individuals are fully aware of their participation in the study, and again, will be put at no risk other than the normal rehab procedures during the compiling of this data. If any questions, please call Kevin Axtman at 1-800-222-7858, assistant director at the Human Performance Center, also Doug Bradford, director of Rehab Services at St. Alexius Medical Center at 1-701-224-7189, or Myron Cullen, assistant director at the Human Performance Center at 1-800-222-7858.

Kevin Axtman, PT/LATC

Doug Bradford, PT
Director of Rehab Services

Richard A. Pschider, FACHE/CEO
St. Alexius Medical Center

LONGITUDINAL OUTCOME STUDY
SURGICAL ROTATOR CUFF PROTOCOL

NAME OF PATIENT_____
Doctor_____DOS___/___/___DOI___/___/___
Preoperative Diagnosis:_____
Surgical Procedure:_____
Surgical Complications:_____
Deltoid Detached: Y/N - Clavicular Resection: Y/N - Graft Used Y/N
Size of the Tear:_____
Age of Patient_____ Sex_____ Involved Side_____ Dominant Side_____
Occupational Injury - Yes_____ No_____
Occupation:_____
Sport Injury - Yes_____ No_____ Sport_____
Injury from other cause (please state):_____
_____

HOSPITAL DISCHARGE
Date___/___/_____ Protocol Title/Date_____
Check off if complete:
_____Pt. was given all protocol instructions prior to discharge.
_____Pt. achieved all discharge parameters satisfactorily.
Alterations from protocol_____
_____
Period and Type of Immobilization_____
_____

PHASE ONE: (2ND TO 3RD WEEK)
Check one: Clinical Care_____ Home Program_____
Date_____ Protocol Date_____
Pain Scale_____
Active Extension of Elbow_____
Active Flexion of Elbow_____
Active Extension of Wrist_____
Active Flexion of Wrist_____
Active Supination of Wrist_____
Active Pronation of Wrist_____
Adducted Passive External Rotation of Shoulder_____
Passive Elevation or Flexion of the Shoulder_____
Complications/Comments: _____
_____
Bilateral Movements Taken: _____Yes _____No
Data Logged: _____Yes _____No # of Visits: _____

PHASE TWO: (6TH WEEK)
Check one: Clinical Care_____ Home Program_____
Date_____ Protocol Date_____
Pain Scale_____
Active Extension of Elbow_____
Active Flexion of Elbow_____
Active Extension of Wrist_____
Active Flexion of Wrist_____
Active Supination of Wrist_____
Active Pronation of Wrist_____
Active Assistive Flexion of the Shoulder_____
Active Assistive Abduction of the Shoulder_____
Active Assistive External Rotation of the Shoulder, (add max. ext. rot. allowed)_____
Passive External Rotation of Shoulder at 90 degrees Abduction, Supine_____
Passive Internal Rotation of Shoulder at 90 Abduction, Supine_____
Passive Elevation or Flexion of the Shoulder, Supine_____
Active Extension of the Shoulder, standing_____
Complication/Comments: _____
_____
Data Logged: _____Yes _____No # of Visits: _____

PHRASE THREE: (12TH WEEK)
Check one: Clinical Care_____ Home Program_____
Date_____ Protocol Date_____
Pain Scale_____
Active Flexion of the Shoulder_____
Active Abduction of the Shoulder_____
Active Adduction of the Shoulder_____
Active External Rotation of the Shoulder at 90 degrees Abduction_____
Active Internal Rotation of the Shoulder at 90 degrees Abduction_____
Active Extension of the Shoulder_____
Passive External Rotation of Shoulder at 90 degrees, Supine_____
Passive Internal Rotation of Shoulder at 90 degrees, Supine_____
Passive Flexion of the Shoulder, supine_____

Manual Muscle Testing (Internal Rotation "IR", External Rotation "ER" in Adducted Position)
_____5 Complete range of motion against gravity with maximum resistance
_____4 Complete range of motion against gravity with moderate resistance
_____3 Complete range of motion with gravity
_____2 Complete range of motion with gravity eliminated
_____1 Evidence of slight contraction, but no joint motion
_____0 No contraction palpated
Complications/Comments: _____
_____
Data Logged: _____Yes _____No -# of Visits: _____

SIX MONTHS POST SURGERY
Current Symptoms: (check each one that applies)
Pain Scale_____ Unusual Sounds_____ Joint Going Back In_____
Swelling_____ Joint Locking Up_____ Inability To Move_____
Stiffness_____ Joint Giving Way_____
External Rotation of Shoulder, 90 Degrees Abduction_____
Internal Rotation of Shoulder, 90 Degrees Abduction_____
Flexion of the Shoulder_____
Extension of the Shoulder_____
Abduction of the Shoulder_____
Adduction of the Shoulder_____
Isokinetic Test/MMT**_____ (Internal/External Rotation)
(include short form)
Joint Play (state your concerns about hyper/hypomobility)
Complications/Comments: _____
_____
Functional Assessment: _____Yes _____No
Data Logged: _____Yes _____No

**Microfet Testing - (test involved and uninvolved)

ONE YEAR POST SURGERY
Current Symptoms: (check each one that applies)
Pain Scale_____ Unusual Sounds_____ Joint Going Back In_____
Swelling_____ Joint Locking Up_____ Inability To Move_____
Stiffness_____ Joint Giving Way_____
External Rotation of Shoulder, 90 Degrees Abduction_____
Internal Rotation of Shoulder, 90 Degrees Abduction_____
Flexion of the Shoulder_____
Extension of the Shoulder_____
Abduction of the Shoulder_____
Adduction of the Shoulder_____
Isokinetic Test/MMT**_____ (Internal/External Rotation)
(include short form)
Joint Play (state concerns about hyper/hypo mobility)
Complications/Comments: _____
_____
Functional Assessment: _____Yes _____No
Data Logged: _____Yes _____No

**Microfet Testing

TWO YEARS POST SURGERY
Current Symptoms: (check each one that applies)
Pain Scale_____ Unusual Sounds_____ Joint Going Back In_____
Swelling_____ Joint Locking Up_____ Inability To Move_____
Stiffness_____ Joint Giving Way_____
External Rotation of Shoulder, 90 Degrees Abduction_____
Internal Rotation of Shoulder, 90 Degrees abduction_____

Flexion of the Shoulder_____
Extension of the Shoulder_____
Abduction of the Shoulder_____
Adduction of the Shoulder_____
Isokinetic Test/MMT**_____ (Internal/External Rotation)
(include short form)
Joint Play (state concerns about hyper/hypo mobility)
Complications/Comments: _____
_____

Functional Assessment: _____Yes _____No
Data Logged: _____Yes _____No

**Microfet Testing

KA/MC/alr
5/96

UPPER EXTREMITY RANGE OF MOTION MEASUREMENTS
NON-INVOLVED EXTREMITY

DATE: _____

(To be used on the first outpatient visit)

Active Flexion of the Wrist_____
Active Extension of the Wrist_____
Active Supination of the Forearm_____
Active Pronation of the Forearm_____
Active Flexion of the Elbow_____
Active Extension of the Elbow_____
Active Flexion of the Shoulder_____
Active Extension of the Shoulder_____
Active Abduction of the Shoulder_____
Active Horizontal Adduction of the Shoulder_____
Active Internal Rotation of the Shoulder_____.
Active External Rotation of the Shoulder_____

REFERENCES:

American Academy of Orthopaedic Surgeons: MEASURING AND RECORDING OF JOINT MOTION, 1963.

Krusen, F.H.; Kottke, F.J.; and Ellwood, P.M. Jr.; eds.: HANDBOOK OF PHYSICAL MEDICINE AND REHABILITATION. Philadelphia, Saunders, 1965, pp. 13-25.

Esch, D. & Leply, M.: MEASUREMENT OF JOINT MOTION: METHODS OF MEASUREMENT AND RECORDING. University of Minnesota Press, 1974.

KA/MC/alr
5/96

UPPER EXTREMITY
FUNCTIONAL ASSESSMENT FORM

DATE: _____

	SATISFACTORY			NON-SATISFACTORY		
ADLs						
Bathing	NA	5	4	3	2	1
Combing Hair	NA	5	4	3	2	1
Shaving	NA	5	4	3	2	1
Dressing	NA	5	4	3	2	1
Eating	NA	5	4	3	2	1
Household Duties						
Cooking	NA	5	4	3	2	1
Cleaning	NA	5	4	3	2	1
Outdoor Activities						
Opening Door	NA	5	4	3	2	1
Driving	NA	5	4	3	2	1
Raking	NA	5	4	3	2	1
Mowing Lawn	NA	5	4	3	2	1
Lifting	NA	5	4	3	2	1
Shoveling	NA	5	4	3	2	1
Sport						
Running - Sprint	NA	5	2	3	2	1
Running - Distance	NA	5	2	3	2	1
Throwing-Long Throw	NA	5	2	3	2	1
Throwing-Short Throw	NA	5	2	3	2	1
Weight Training	NA	5	2	3	2	1

KA/MC/alr
5/96

APPENDIX D

ST. ALEXIUS MEDICAL CENTER

SURGICAL ROTATOR CUFF PROTOCOL

JANUARY 1997

A. PREOPERATIVE SCREENING/INSTRUCTION

1. Rehabilitation for the rotator cuff repair will vary in length depending on several factors such as:
   a. Age of the patient
   b. Acute versus chronic tear
   c. Size and/or location of tear
   d. Immobilization time (use of abduction splint)
   e. Preoperative strength/ROM status
   f. Associated injuries/surgeries
   g. Desired activity level
2. Teach exercise program (Day 1)

B. PRECAUTIONS

1. Portion of anterior deltoid muscle detached/split
   a. Avoid active forward flexion for a minimum of 4-6 weeks
2. Sling at side 3-6 weeks, or axillary bolster/abduction splint 4-8 weeks
3. Obtain operative report for nature of repair
   a. Phase I may take 3-4 weeks for those undergoing direct repair, versus 6-8 weeks for those who have had a large/massive tear or tenuous repair, or need an abduction brace postoperatively.

900 East Broadway Box 5510
Bismarck, North Dakota 58506-5510
701-224-7000
FAX 701-224-7284
TDD 701-224-7946

SURGICAL ROTATOR CUFF PROTOCOL
PAGE 2

4. Usually takes 6-12 months for a full recovery, occasionally will improve for up to 2 years postop

C. GOALS

1. Painless shoulder

2. Functional active range of motion obtained by end of 3rd month

   a. Minimum functional shoulder range: Flexion to 100 degrees, abduction to 90 degrees, external rotation to 45 degrees.

3. Functional strength returns

REHABILITATION

Phases of program based on stages of soft tissue healing (Review)

I. Phase I - 0 to 3 Weeks Postop (May take up to 6 weeks before advancement) Physician initiates program depending on repair, usually begun postop 2-4 days

0 to 10 days: Inflammatory stage, work on pain relief

10 days to 3 weeks: Coincides with fibroplasia stage of soft tissue healing

A. Passive range of motion

1. Six times daily, immobilizer removed for exercises

2. Pendulum exercises

3. Passive external rotation to pain free tolerance

   a. Arm adducted with towel roll between arm and side

4. Pulleys

   a. Do in plane of scapula for elevation to tolerance (Avoid any type of shoulder hiking)

SURGICAL ROTATOR CUFF PROTOCOL
PAGE 3

B. Active range of motion

1. Cervical spine AROM
2. Elbow (Precaution if biceps repaired)
3. Wrist and hand
   a. Watch for hand swelling
   b. Watch for possible ulnar nerve irritation or olecranon bursitis from leaning on elbow

C. Modalities for pain relief (ice, E-stim, etc.)

D. Goals for Phase I

1. Promote functional scar
2. Increase ROM; 30-45 degrees passive external rotation in neutral, 90 degrees passive elevation
3. Prevent neuro dissociation

* Physician will notify if sling to be sent home upon discharge.

II. Phase II - Start at 3-4 To 8 Weeks Postop

Sling may be removed at this time (physician discretion)

Coincides with late fibroplasia stage.

A. Educate in anatomy, surgical technique and rehab phase

B. Continue passive range of motion

C. Continue with AROM of distal joints

D. Assisted PROM all motions to pain free tolerable range

1. Supine assisted passive flexion with use of cane

SURGICAL ROTATOR CUFF PROTOCOL
PAGE 4

2. Supine external rotation starting with 45 degrees of abduction and progressing to 90 degrees of abduction

3. Supine 135 degrees of abduction/external rotation with use of cane

E. Active internal/external rotation with elbow adducted

F. Active exercises

1. Shoulder shrugs

2. Prone rowing

3. Biceps curl (observe any precautions)

4. Triceps curl

5. Active assisted/active flexion after 6-8 weeks to 90 degrees

6. Shoulder abduction to 70 degrees active assisted/ actively after 6 weeks observing scapulohumeral rhythm

G. Mobilization of capsule/clavicle/scapula p.r.n.

H. Modalities for pain relief

1. Ice with arm supported slightly abducted

I. Proprioceptive activities

III. <u>Phase III - Start at 8 to 12 Weeks Postop</u>

Early maturation stage

Functional scar at 6 weeks postop

Full PROM by 9 weeks postop: flexion 140°-160°; external rotation 70°-80° at 90° abduction

SURGICAL ROTATOR CUFF PROTOCOL
PAGE 5

A. Continue ROM

1. Active ROM flexion to tolerance
2. Active ROM abduction to 90 degrees

B. Stretches

1. Posterior cuff stretch
2. Inferior cuff stretch
3. Internal rotation stretch

C. Continue mobilization p.r.n.

D. Gentle resistive exercises to individual rotator cuff muscles and scapular stabilizers after appropriate active motion achieved

1. Shoulder shrugs
2. Flexion resisted to 90 degrees.
3. Scaption with external rotation
4. Internal rotation in the adducted position to full with use of low resistance Theraband.
5. External rotation adducted with low resistance Theraband (to neutral only if instability present)
6. Prone rowing
7. Biceps curl (observe any precautions)
8. Triceps curl

E. UBE

F. Modalities for pain relief

SURGICAL ROTATOR CUFF PROTOCOL
PAGE 6

IV. Phase IV - 12 to 16 Weeks Postop

Maturation Stage

A. Continue ROM activities p.r.n.

B. Continue mobilization p.r.n.

C. Resisted exercises

1. Progressive resistive exercises through available ROM.

a. Keep arm in front and below shoulder level for strengthening exercises if progress is slow/ painful

b. Resisted abduction beyond 70 degrees as well as elevation beyond 90 degrees should be avoided until internal rotation/external rotation is 25% or less deficit compared to the uninvolved side

2. Additional strengthening for rotator cuff as well as scapular musculature.

a. Flexion (full) - Must be able to elevate actively without shoulder hiking before advancing resistance.

b. Scaption with external rotation

c. Scaption internally rotated

d. Rowing prone

e. Horizontal abduction prone with ER

f. Wall pushup with plus

g. Resisted internal/external rotation in the adducted position progressing to more abducted positions depending on desired activity level to be returned

D. UBE

SURGICAL ROTATOR CUFF PROTOCOL
PAGE 7

4. Cybex

a. Avoid 0 degrees adducted or 90 degrees abducted initially (suggest internal rotation with 20 degrees of abduction or in plane of scapula, external rotation up to 90 degrees flexion or also do in plane of scapula).

D. Modalities for pain relief

V. Phase V - 16 Weeks Postop to Discharge

Coincides with maturation stage

A. Maintenance program for nonathletic patients

B. Functional progression for throwing athletes

1. Discharge to Human Performance Center Throwing Program

CLINICAL REVIEWER MEDICAL REVIEWER

CLINICAL DIRECTOR MEDICAL DIRECTOR

KA/alr
1/2/97

B I B L I O G R A P H Y

ROTATOR CUFF PROTOCOL
Conservative/Surgical Rotator Cuff and Partial Acromioplasty

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APPENDIX E

	ID #	Gender	Age	Days	Tear Size	SurgType	Dom Hand	Ptist	MD	Phase
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Pain	A-Flex	A-Abd	A-ER-90	A-IR-90	P-ER-Add	P-ER-90	P-IR-90	P-Flex	MMT	MF-inv
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APPENDIX F

University of California at Los Angeles End-Result Scores

	Points
PAIN	
Present all of the time and unbearable; strong medication frequently	1
Present all of the time but bearable; strong medication occasionally	2
None or little at rest, present during light activities; salicylates frequently	4
Present during heavy or particular activities only; salicylates occasionally	6
Occasional and sight	8
None	10
FUNCTION	
Unable to use limb	1
Only light activities possible	2
Able to do light housework or most activities of daily living	4
Most housework, shopping, and driving possible; able to do hair and dress And undress, including fastening brassiere	6
Slight restriction only; able to work above shoulder level	8
Normal activities	10
ACTIVE FORWARD FLEXION	
150 degrees or more	5
120 to 150 degrees	4
90 to 120 degrees	3
45 to 90 degrees	2
30 to 45 degrees	1
Less than 30 degrees	0
STRENGTH OF FORWARD FLEXION	
Grade 5 (normal)	5
Grade 4 (good)	4
Grade 3 (fair)	3
Grade 2 (poor)	2
Grade 1 (trace)	1
Grade 0 (nothing)	0
SATISFACTION OF PATIENT	
Satisfied and better	5
Not satisfied and worse	0
MAXIMUM SCORE	35

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